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(12) **United States Patent**
Bandeian, Jr. et al.

(10) **Patent No.: US 6,445,304 B1**
(45) **Date of Patent: Sep. 3, 2002**

(54) **MEDICAL ALARM SYSTEM**

(76) Inventors: **John J. Bandeian, Jr.; John J. Bandeian, III**, both of 3169 W. State St., Bristol, TN (US) 37620

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/636,376**

(22) Filed: **Aug. 11, 2000**

(51) **Int. Cl.**[7] **G08B 21/00**
(52) **U.S. Cl.** **340/604**; 340/605; 600/371
(58) **Field of Search** 340/604; 128/638; 304/605; 600/307, 371, 547

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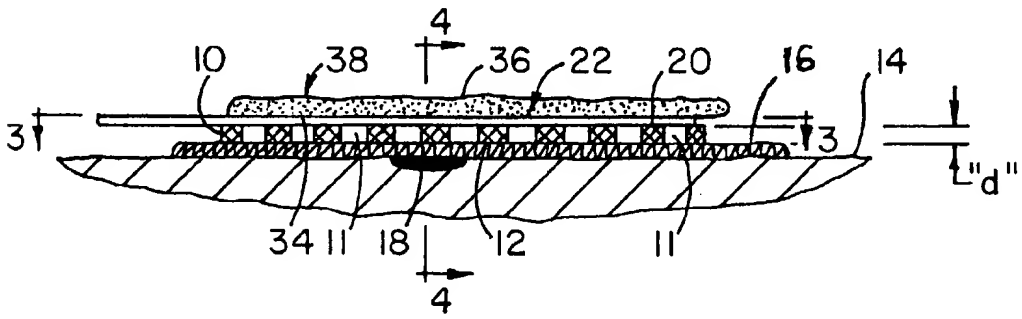
Primary Examiner—Edward Lefkowitz

(57) **ABSTRACT**

A monitoring and alarm system for detecting excessive bleeding from medical patients and for alerting medical attendant(s) thereof, the system comprises a relatively thick sheet-like base of electrically non-conductive, blood porous material having a proximal side adapted for mounting directly on a patients skin or on a porous protective gauze or bandage or the like thereon at a site on the patients body where heavy bleeding can occur due to inadvertent opening of a wound or incision, or due to inadvertent extraction of a syringe, I.V. tube, catheter or the like, the base has a distal side, a normally open electrical circuit positioned adjacent the distal side and spaced from the proximal side a predesigned distance, electrically actuable visual, sound or physical alarm electrically connected into the circuit, and electrical switching for the circuit responsive to contact with blood to close the circuit and actuate the alarm to alert the medical attendant(s) to the excessive bleeding.

16 Claims, 1 Drawing Sheet



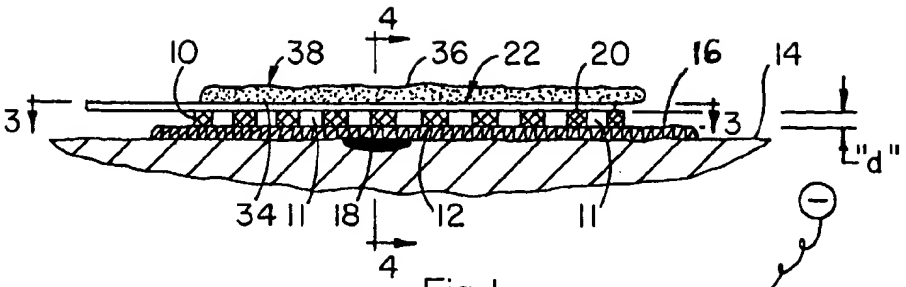


Fig. 1

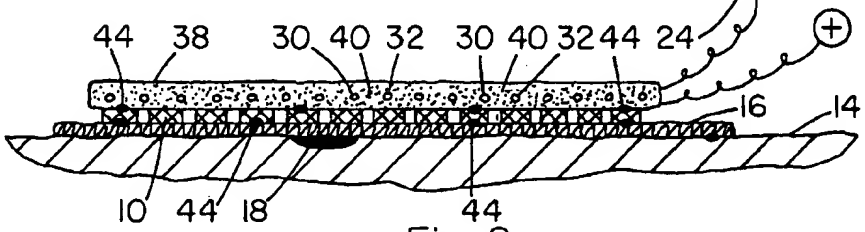


Fig. 2

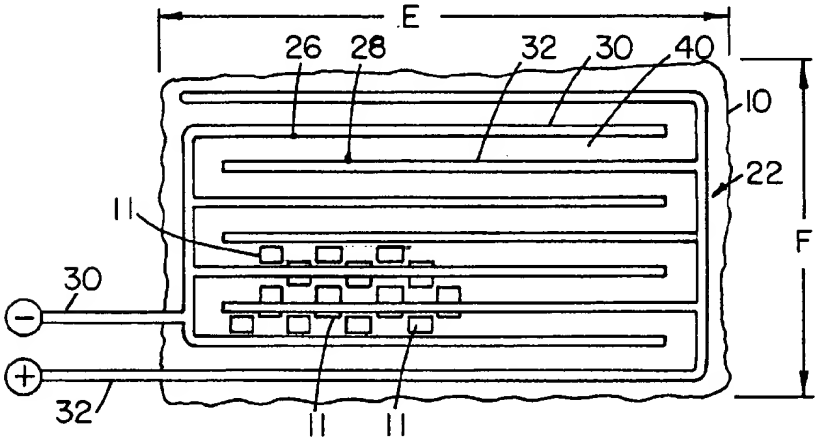


Fig. 3

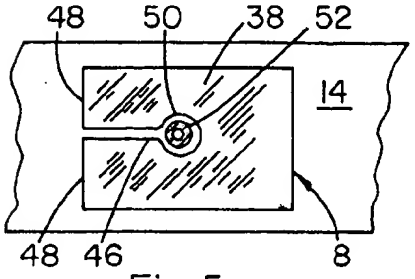


Fig. 5

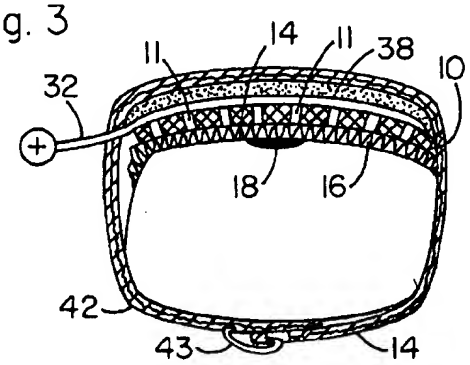


Fig. 4

MEDICAL ALARM SYSTEM

BACKGROUND OF THE INVENTION

1. Field

This invention concerns medical alarm systems and particularly systems which can quickly detect and warn the patient himself, the medical staff, or other attendants who may be caring for the patient, e.g., at home or in a hospital, of unexpected excessive or heavy bleeding such as can occur when a wound or incision reopens unexpectedly or when a medical device such as an I.V. tube, syringe, catheter or the like is untimely or inadvertently pulled from a patients artery or vein.

2. Prior Art

Applicant is unaware of any prior systems or devices which are designed to function as described above.

SUMMARY OF THE INVENTION

The invention in one of its preferred embodiments is defined as a monitoring and alarm system for detecting excessive or heavy bleeding from medical patients and for alerting medical attendant(s) wherein the system utilizes a relatively thick sheet-like blood porous base element of electrically non-conductive blood porous material having a proximal side adapted for mounting directly on a patients skin or on a blood porous protective gauze or bandage thereon at a site on the patients body where excessive bleeding can occur unexpectedly, the base having a distal side supporting a normally open electrical circuit, electrically actuable alarm means electrically connected into electrical circuit, electrically actuable alarm means electrically connected into the circuit, and electrical switching means for the circuit responsive to contact with blood to close the circuit and actuate the alarm means to alert said medical attendant(s) to said excessive bleeding.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be further understood from the drawings and description herein, wherein:

FIG. **1** is a cross-sectional view of one preferred embodiment of the present system positioned on a patients arm over the site of a wound or incision;

FIG. **2** is a view as in FIG. **1** showing a variation in the electrical circuit mounting;

FIG. **3** is a view of one exemplary type of electrical circuit useful in the present invention taken along line **3**—**3** of FIG. **1** in the direction of the arrows with only a representative number of pores shown in the base means;

FIG. **4** is a cross-sectional view taken along line **4**—**4** of FIG. **1** in the direction of the arrows and showing a wrap means for attaching the present system to a patients limb or body; and

FIG. **5** is a top view of a special shape for the present system.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to the drawings and with particular reference to the claims hereof, the present system generally designated **8** comprises a relatively thick sheet-like base means **10** of electrically non-conductive, blood porous material having a proximal side **12** adapted for mounting directly on a patients skin **14** or on a porous protective gauze, bandage or other such porous medical item **16** thereon at a site **18** on the

patients body where bleeding can occur, said base means having a distal side **20** with a a predesigned distance "d", electrically actuable visual, sound or physical alarm means **24** electrically connected into said circuit means, and electrical switching means comprising any adjacent electrical contact portions anywhere along electrical conductors **30** and **32** such as **26,28** in said circuit means responsive to bridging contact with blood to close said circuit means and actuate said alarm means to alert medical attendant(s) to said excessive bleeding.

The base **10** must be of electrically non-conductive material such as polyolefins, PVC, polyester, urethanes, natural or synthetic rubbers or elastomers, any of which may be plastisols or which preferably are of foamed cellular structure to provide substantial flexibility and softness to the base. The base is preferably configured as a flexible netting type structure having a thickness of from about 1/32 to about 3/16 in., and having from about 6 to about 20 pores 11 per inch, most preferably from about 9 to about 16 pores per square inch, and wherein said pores average in area from about 0.002 to about 0.02 in^2, most preferably from about 0.005 to about 0.01 in^2. The pores can be of any shape including square, rectangular, round or oval. The manufactured dimensions E and F of the system is determined by the area to be monitored and can range, for example, from a square inch to 50 or more square inches.

The essential character of the base is that the pores must allow free flow of blood from the bleed site **18** to bridge the gap between the conductors **30,32** of the circuit **22**. The sensitivity of the system to bleeding can, of course, be increased by reducing the values of "d", e.g., by reducing the thickness of the base. This base thickness, while having an allowable wide dimensional range, should not be so thin as to allow normal or expected fluid leakage from the site to easily fill up the pores and bridge the circuit conductors, whether an intermediate barrier such as gauze **16** is used or not.

It is noted that the present system is intended to be placed on the patient such that the blood would have to flow or migrate substantially upwardly against the force of gravity to reach the electrical circuit. Such placement more easily guarantees that casual seepage of blood or other body fluid from site **18** would not trigger the alarm, particularly where an intermediate absorptive element such as **16** is employed.

The electrical circuit **22** in a simple but very efficient form as shown in FIG. **4** consists of side by side conductor **30,32** which may be supported by and held directly on the distal side **20** of the base. These conductors may also be supported on either the proximal **34** or distal side **36** of a support such as **38**, or encased by said support. This support, preferably, is highly absorptive of blood and constructed to allow rapid migration of blood throughout the support for bridging a gap such as **40** between the conductors.

The spacing of the conductors should be sufficiently small to allow blood to readily complete the circuit. Spacings of from about 0.1 to about 0.75 in., have been found to operate with great rapidity for a more than small or casual blood flow. In this regard, it is apparent that extremely sensitive switch means employing relays or the like in the circuitry can be employed to operate the alarm on very low electrical sensing or switching current flowing between the conductors. The use of low voltage battery sensing or switching power, e.g., 1–9 volts, is preferable, and, of course, can be relayed into house or hospital wiring, if desired.

The type of alarm is readily selected by one skilled in the art and can be, for example, flashing lights, ringing bell, or

even the physical jostling of a chair or the like in which an attendant may be sitting, whether in or out of a hospital setting. An effective sound alarm is the Model BWD-HWA WATCHDOG WATER Alarm marketed by Glentronics, Inc., Glenview, Ill.

Referring to FIG. **4**, a wrap means **42** such as an Ace bandage and securement clip **43** or the like may be employed to hold the system to the patients arm, leg, or even torso or other body part. It is noted that the present system, particularly in embodiments where the various elements such as **16**, **10**, **22** and **38** are pre-assembled as a unit, can be placed in any exterior location on the body such as adjacent any body orifice and operate effectively to detect and alarm for excessive bleeding. In this regard, such a unit can be provided with adhesive material, preferably water insoluble and of adhesive bandage type, around the edges of the base or gauze for convenient attachment to the skin such as at locations **44**.

Referring to FIG. **5** the present system **8** is configured with a slot or split **46** which extends from one edge **48** to an inner aperture such as **50** which passes completely thru the system from top to bottom. This aperture can be tailored in size and shape to accommodate a medical item **52** such as an I.V. tube, catheter or the like which is affixed into a patients vascular system.

This invention have been described in detail with particular reference to preferred embodiments thereof, but it will be understood that variations and modifications will be effected within the spirit and scope of the invention.

We claim:

1. A monitoring and alarm system for detecting excessive bleeding from medical patients and for alerting medical attendant(s) thereof, said system comprising a relatively thick sheet-like base means of electrically non-conductive, blood porous material having a proximal side adapted for mounting directly on a patients skin or on a porous protective gauze or bandage thereon at a site on the patients body where heavy bleeding can occur due to inadvertent opening of a wound or incision or due to inadvertent extraction of a syringe, I.V. tube, catheter or other invasive medical implement, said base means having a distal, a normally open electrical circuit means positioned adjacent said distal side and spaced from said proximal side a predesigned distance, electrically actuable visual, sound or physical alarm means electrically connected into said circuit means, and electrical switching means for said circuit means responsive to contact with blood to close said circuit means and actuate said alarm means to alert said medical attendant(s) to said excessive bleeding.

2. The system of claim **1** wherein said circuit means comprises at least two spaced apart electrical conductors positioned adjacent said distal side of said base means, wherein one conductor is connected to a power lead and the other conductor is connected to a ground lead of a power source, and wherein said switching means comprises at least one gap between contact portions of said spaced conductors and adapted to be bridged by electrolytic blood to electrically connect said contact portions.

3. The system of claim **2** wherein said power source is selected from the group selected from battery power, house, clinic or hospital power, or generator power.

4. The system of claim **2** wherein said conductors are mounted on or imbedded in a non-conductive support means having a high capacity for blood absorption and migration.

5. The system of claim **4** wherein said support means is affixed to said distal side of said base means, and wherein said base means is comprised of a flexible netting type structure having a thickness of from about 1/32 to about 3/16 in., and having from about 6 to about 20 pores per square inch, wherein said pores average in area from about 0.002 to about 0.02 in^2.

6. The system of claim **5** wherein the material of said netting is comprised substantially of a material of the group consisting of polyolefin, PVC, polyester, polyurethane, or natural or synthetic rubber or elastomers.

7. The system of claim **4** wherein the material of said support means comprises a mat of natural fibers.

8. The system of claim **4** wherein the material of said support means comprises a mat of felt.

9. The system of claim **4** wherein the material of said support means comprises a mat of blood absorptive paper.

10. The system of claim **4** wherein the material of said support means comprises a mat of blotter paper.

11. The system of claim **4** wherein said support means is physically attached to said base means by electrically non-conductive connector means.

12. The system of claim **1** wherein the material of said base means is substantially blood non-absorptive.

13. The system of claim **11** wherein wrap means is provided on said support means for making quick and stable attachment of said system to a patients body.

14. The system of claim **13** wherein the material of said base means is substantially blood non-absorptive.

15. The system of claim **11** wherein a layer of blood absorbing medical gauze is affixed to the proximal side of said base means to thereby provide a unitary bandaging and bleeding alarm unit.

16. The system of claim **15** wherein wrap means is provided on said support means for making quick and stable attachment of said system to a patients body.

* * * * *

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(12) **United States Patent**
Eliasen et al.

(10) **Patent No.: US 6,332,874 B1**
(45) **Date of Patent: Dec. 25, 2001**

(54) **COUPLING AND STABILIZATION SYSTEM FOR PROXIMAL END OF CATHETER**

(75) Inventors: **Kenneth A. Eliasen**, Queensbury, NY (US); **Kelly B. Powers**, North Salt Lake; **Daniel T. Schlehuber**, Sandy, both of UT (US)

(73) Assignee: **C.R. Bard, Inc.**, Murray Hill, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/143,275**

(22) Filed: **Aug. 28, 1998**

Related U.S. Application Data

(63) Continuation-in-part of application No. 29/091,063, filed on Apr. 20, 1999, now Pat. No. Des. 408,530.

(51) **Int. Cl.**[7] **A61M 5/32**

(52) **U.S. Cl.** **604/174**; 128/DIG. 6; 128/DIG. 26

(58) **Field of Search** ..... 604/174, 177, 604/179, 180, 164, 165, 164.01–164.02, 164.04, 164.13–165.01, 165.03; 128/DIG. 6, DIG. 26

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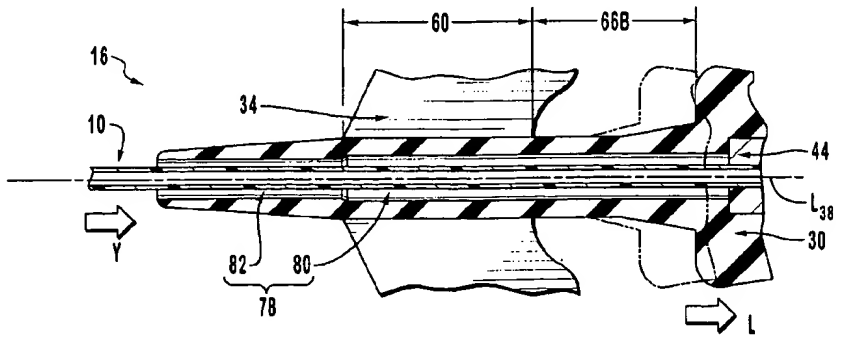
Primary Examiner—Richard K. Seidel
Assistant Examiner—LoAn H. Thanh
(74) *Attorney, Agent, or Firm*—TraskBritt

(57) **ABSTRACT**

A conduit of relatively tough biocompatible material encloses a longitudinally extending fluid flow lumen and has a distal end configured as a catheter coupling hub. The conduit is encircled at the distal end of the catheter coupling hub and a portion of the conduit distal of and adjacent to the catheter coupling hub by a stabilization sleeve made of a contrastingly resilient, soft material suitable for skin contact applications. A pair of stabilization wings extends laterally on opposite sides from the stabilization sleeve at an attachment location separated from the portion of the stabilization sleeve in which the catheter coupling hub is received. As a result, a strain relief region is created. The stabilization sleeve is permanently attached to the conduit at the coupling hub only. The portion of the conduit distal of and adjacent to the catheter coupling hub extends slideably through the remainder of the length of the stabilization sleeve affording axial and bending strain relief to that portion of the conduit.

38 Claims, 9 Drawing Sheets



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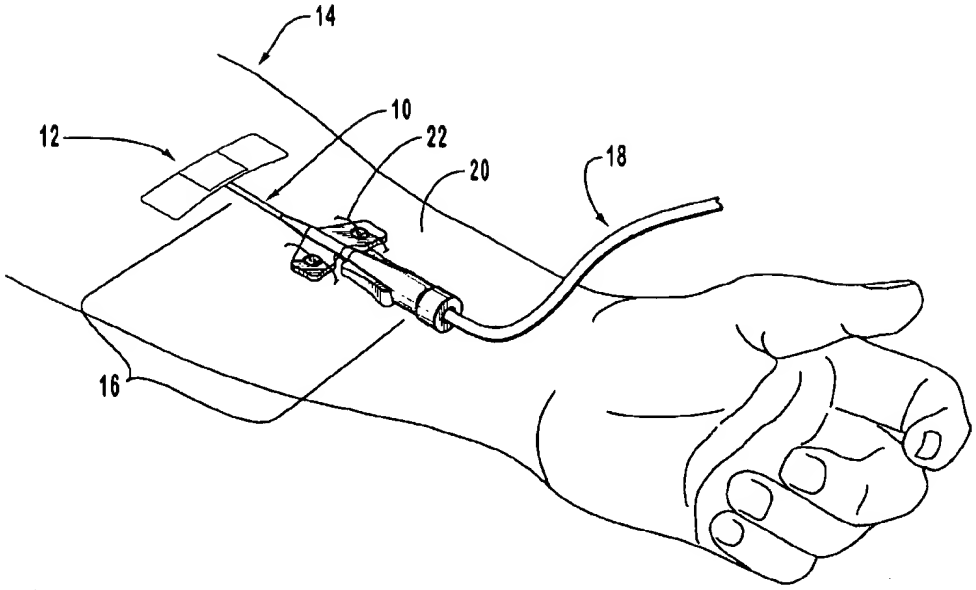
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FIG. 1

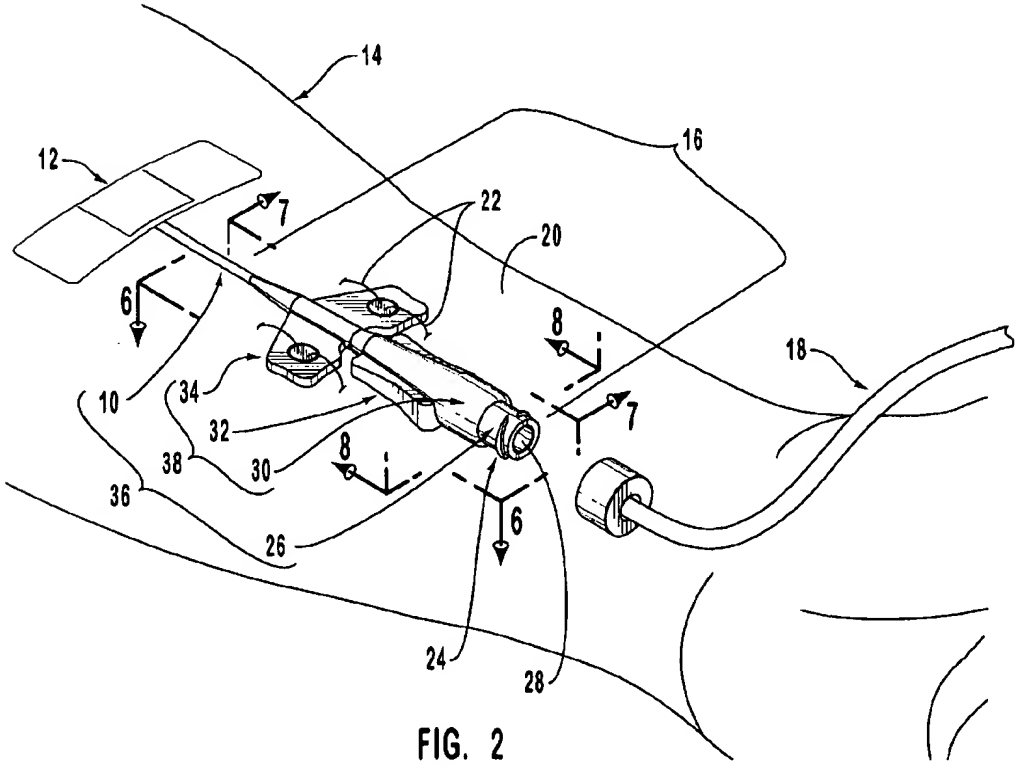
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FIG. 2

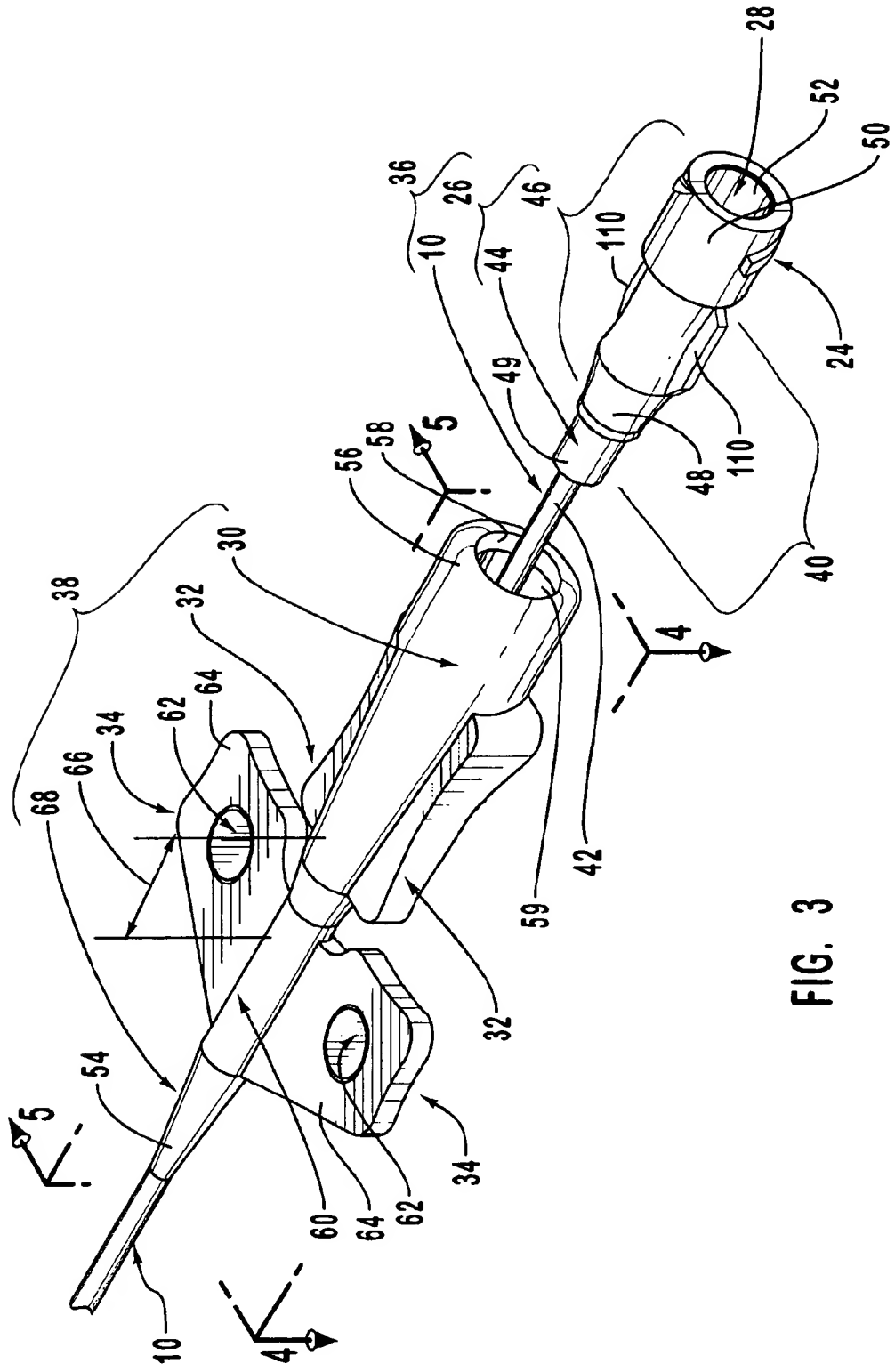
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FIG. 3

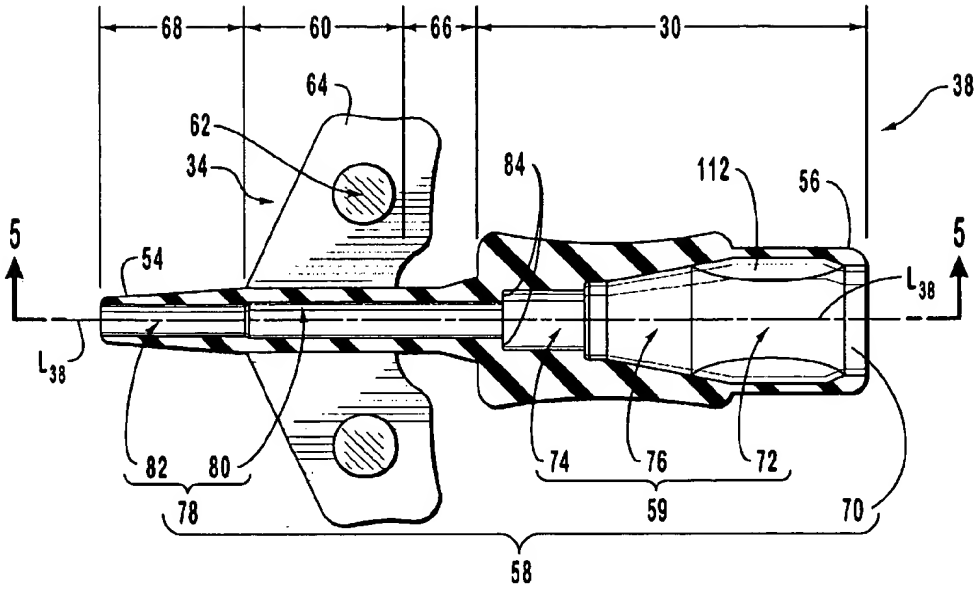
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FIG. 4

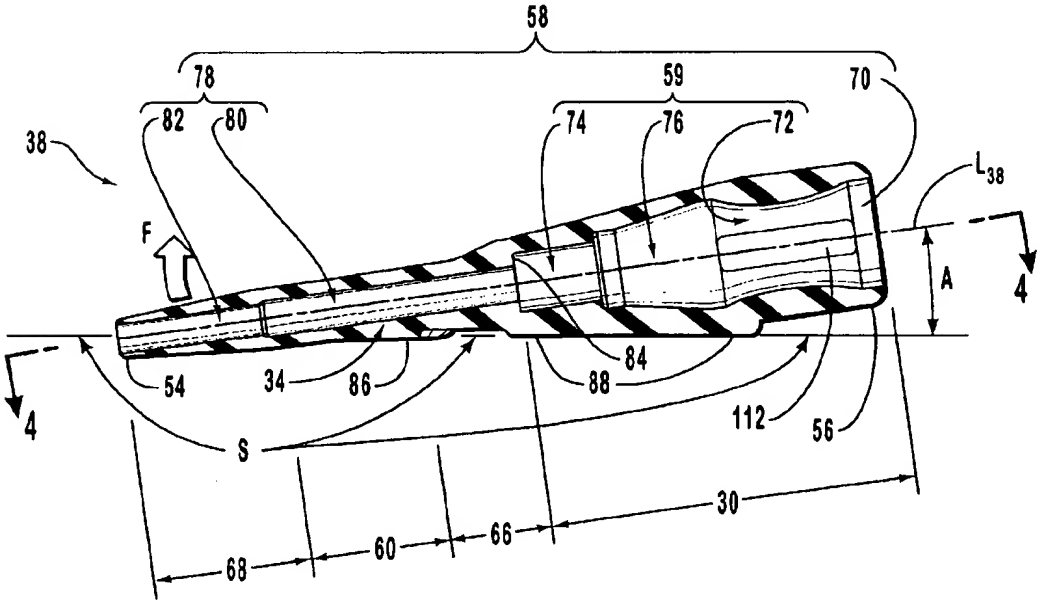
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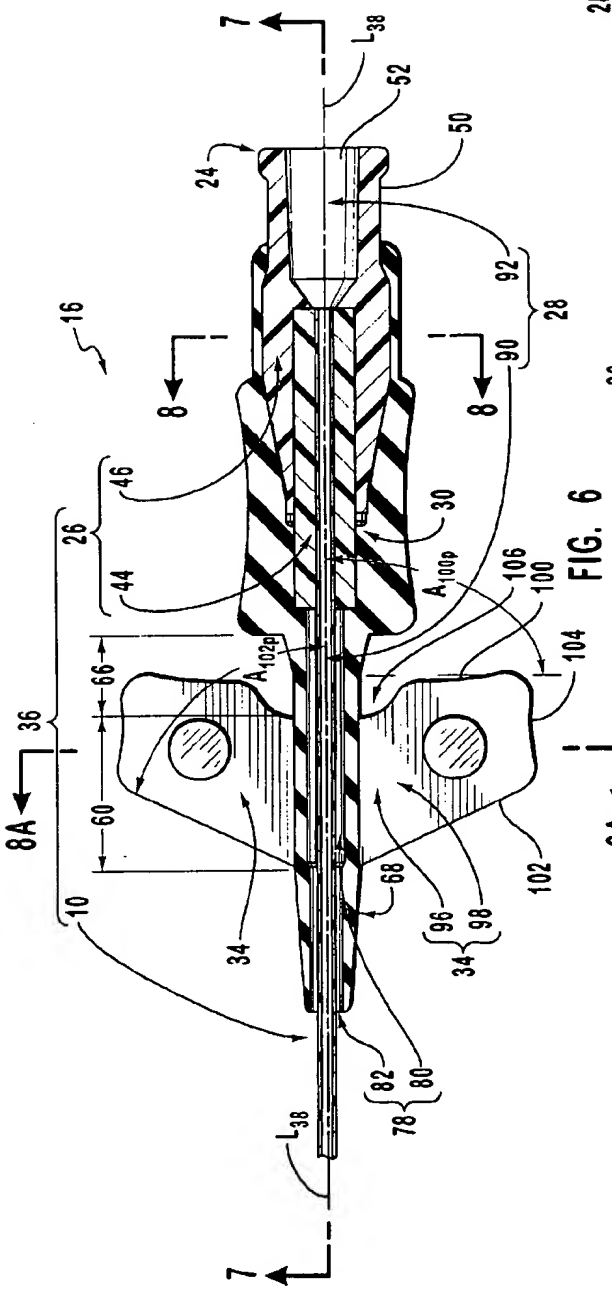
FIG. 5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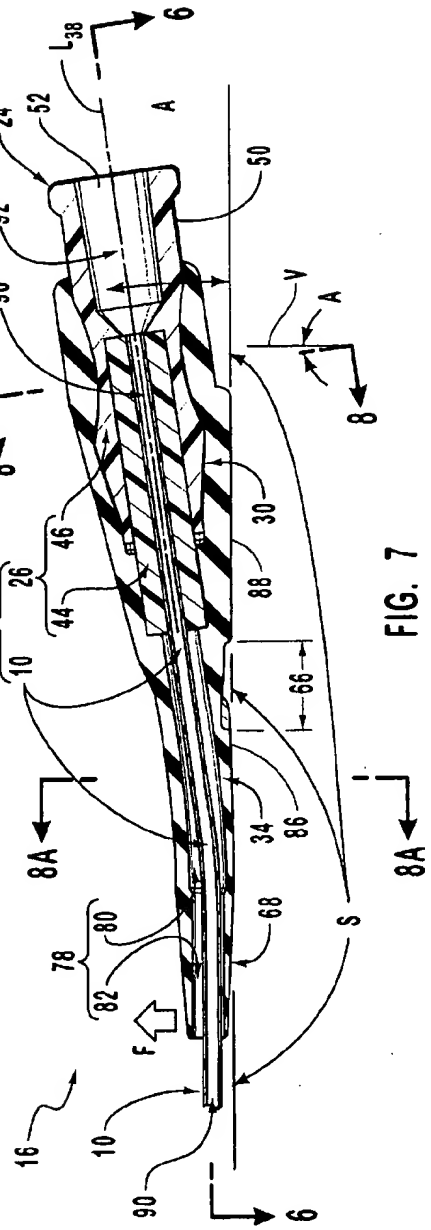
28
90
8
46
26
44
30
A_{100p}
106
100
104
A_{102p}
66
36
8A
60
10
34
68
96
98
102
82
80
78

FIG. 6


6
L_{38}
52
24
A
50
28
92
90
V
8
30
46
88
26
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36
10
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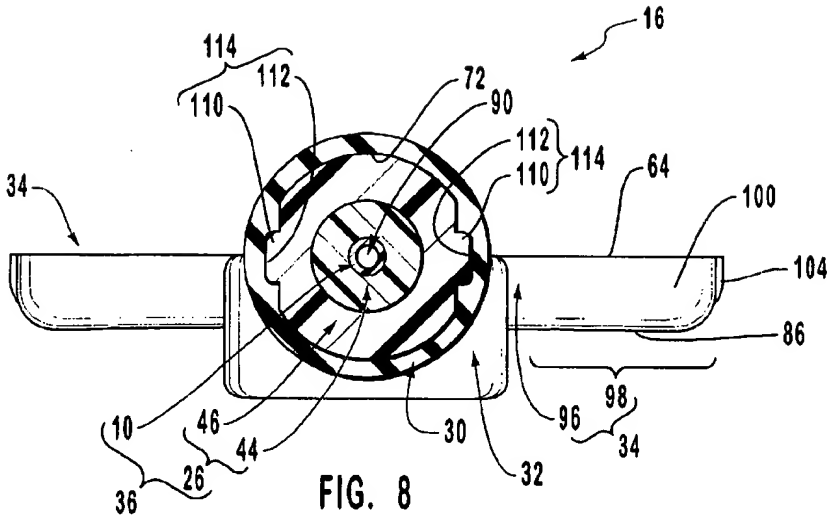
8A
68
78
80
82
S
F
16
10
90

FIG. 7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114
112
110
72
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86
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96
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10
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44
30
32
26
36

FIG. 8

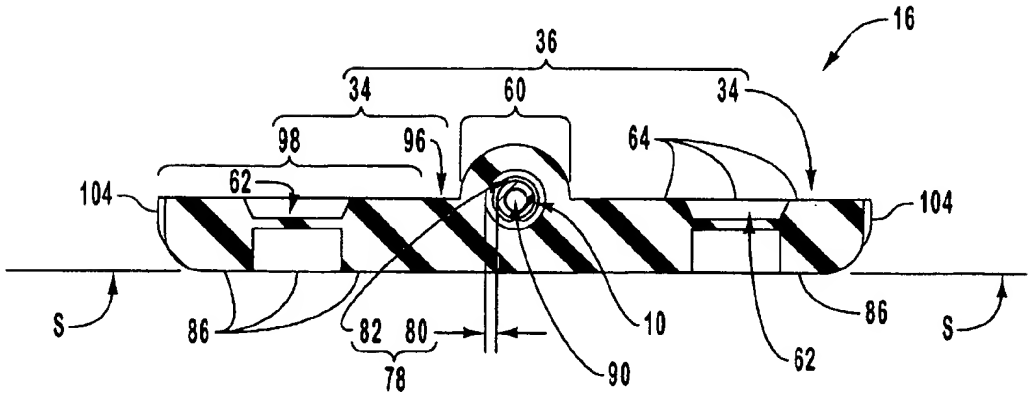
16
36
34
60
34
98
96
64
62
104
104
S
86
82
80
78
10
90
62
86
S

FIG. 8A

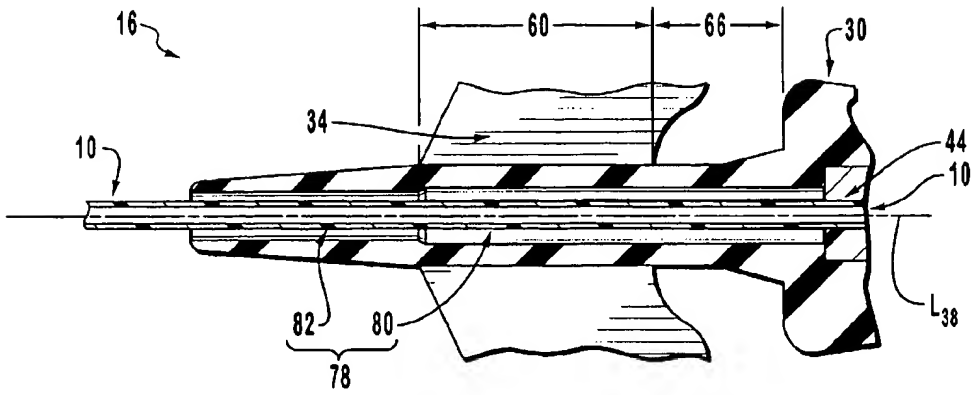

FIG. 9A

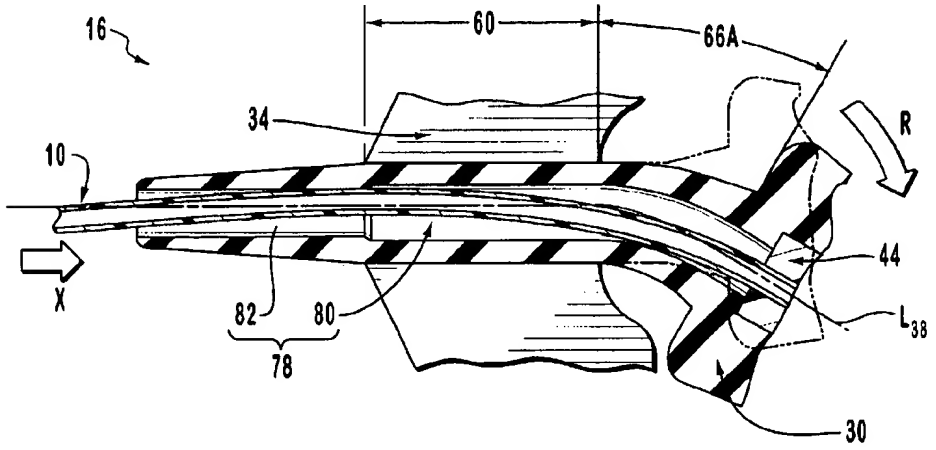

FIG. 9B

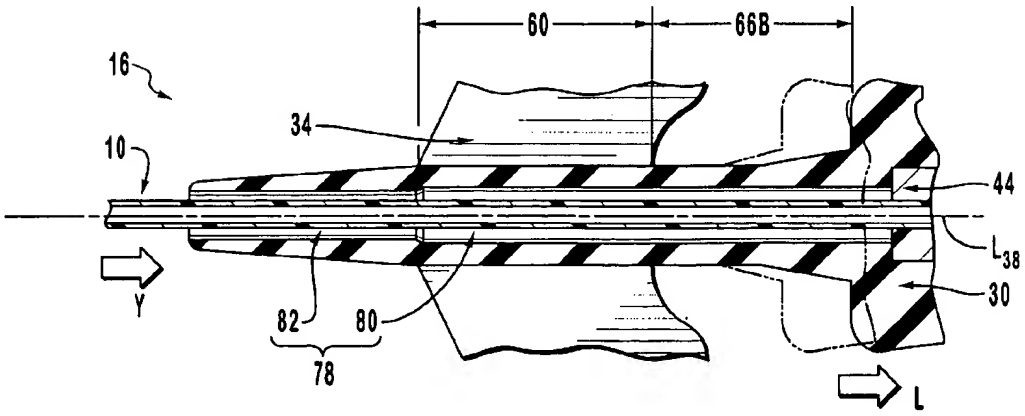

FIG. 9C

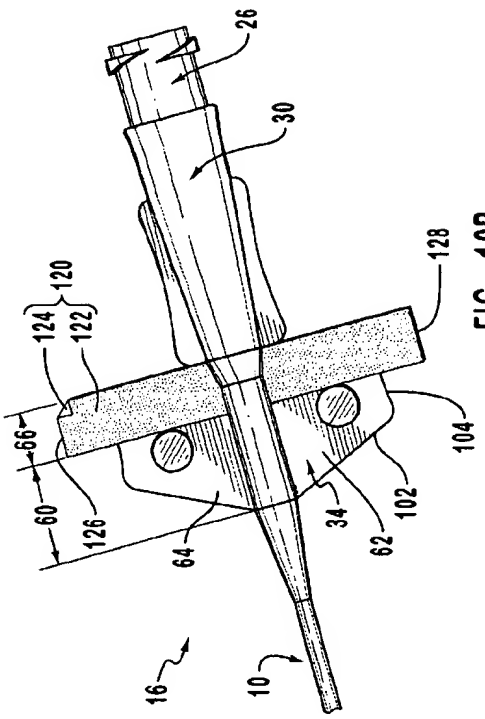

FIG. 10B

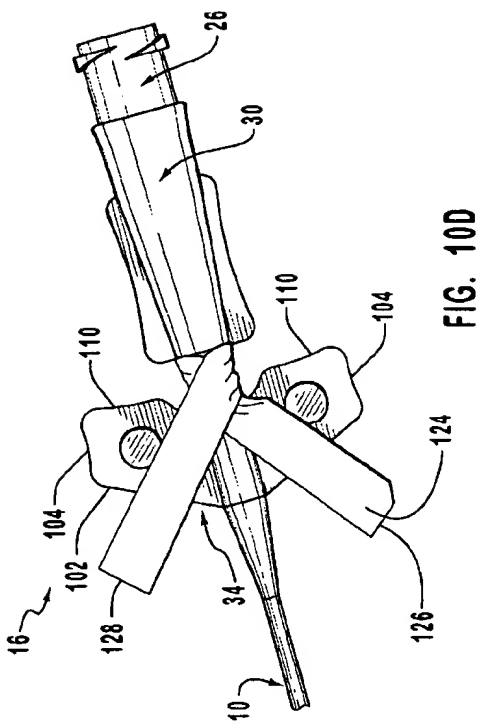

FIG. 10D

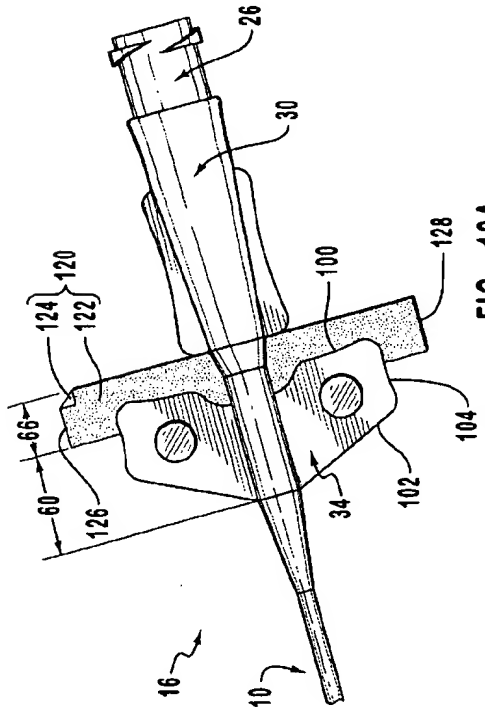

FIG. 10A

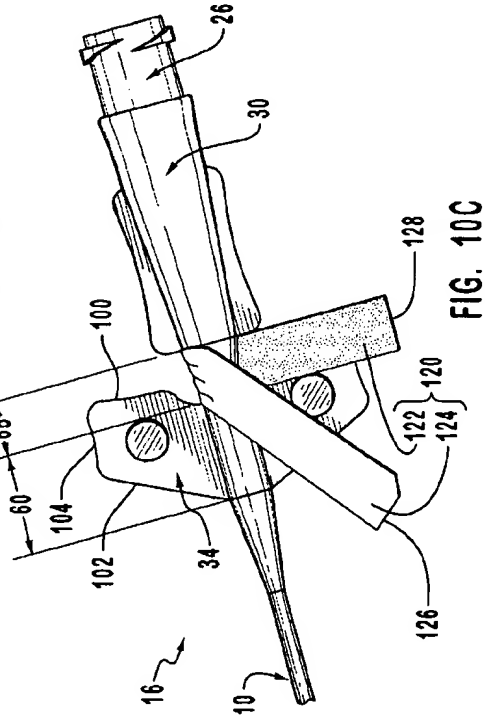

FIG. 10C

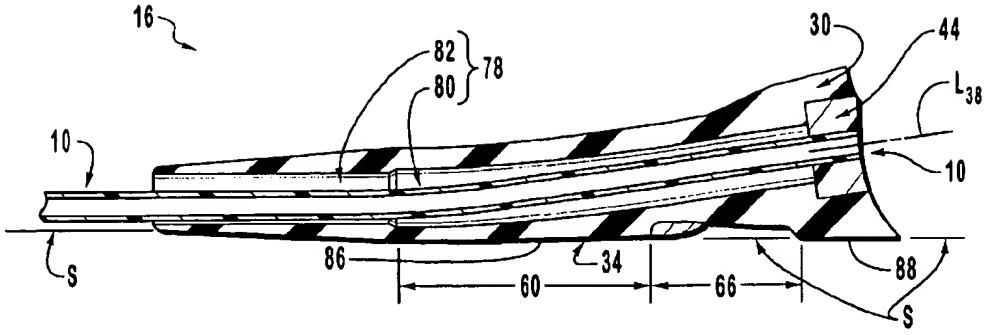

FIG. 11A

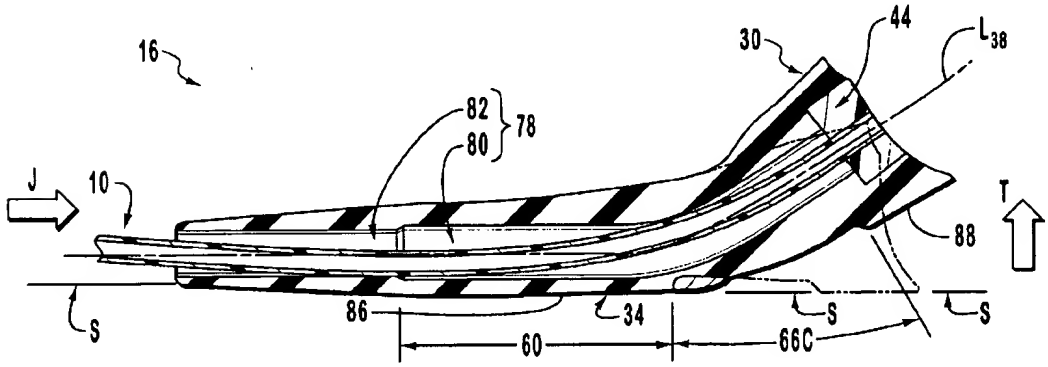

FIG. 11B

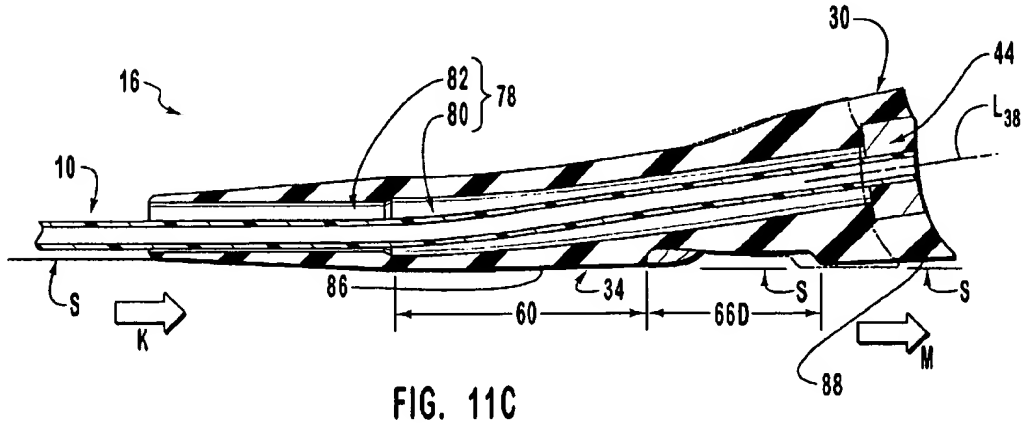

FIG. 11C

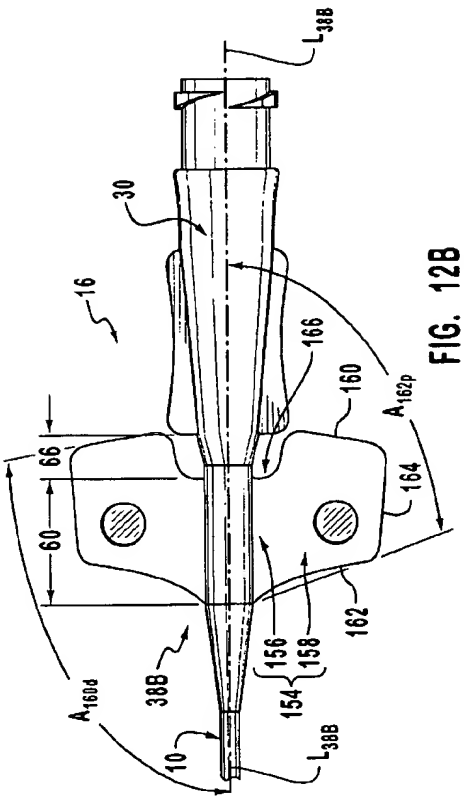

FIG. 12B

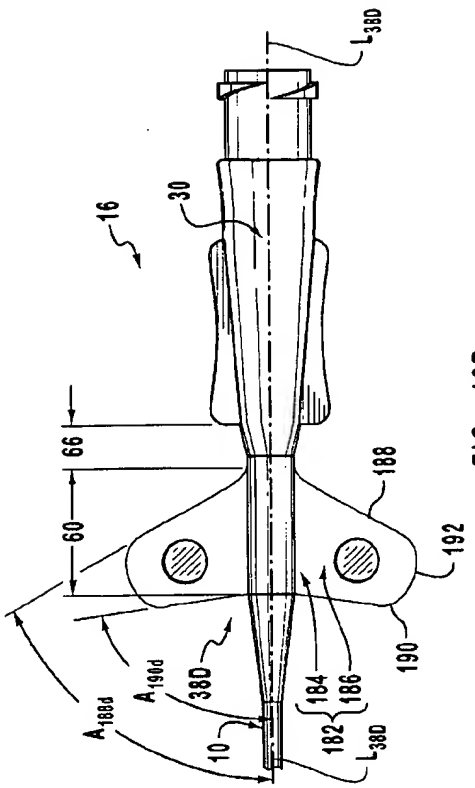

FIG. 12D

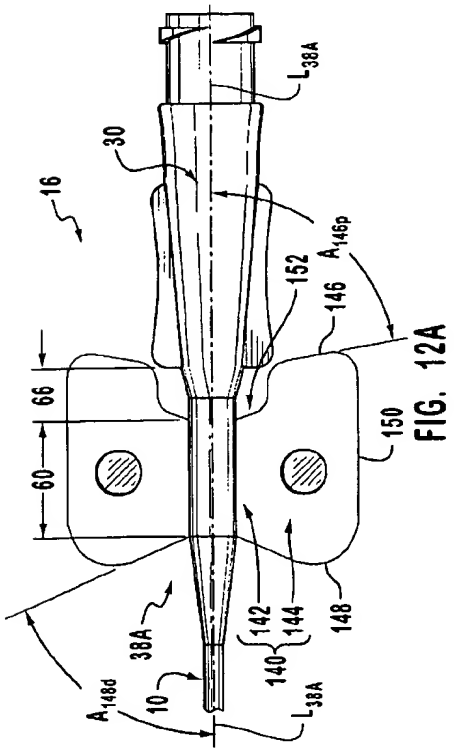

FIG. 12A

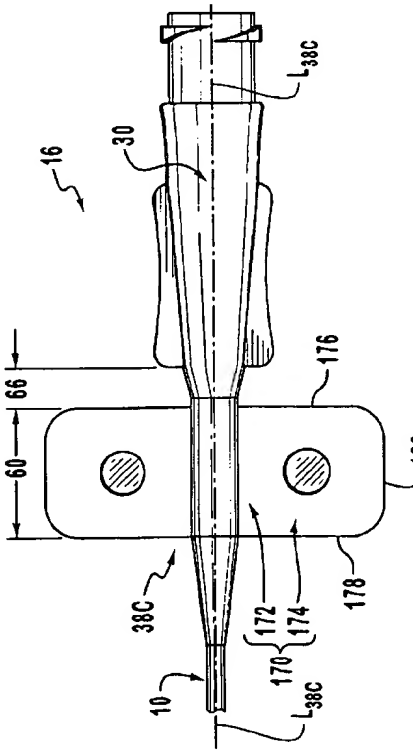

FIG. 12C

COUPLING AND STABILIZATION SYSTEM FOR PROXIMAL END OF CATHETER

RELATED APPLICATIONS

This is a United States continuation-in-part application of U.S. appl. Ser. No. 29/091063, filed Apr. 20, 1999 now U.S. Pat. No. Des. 408,530 that issued on Apr. 20, 1999, from U.S. Design patent application Ser. No. 91,063 that was filed on Jul. 22, 1998.

BACKGROUND

1. The Field of the Invention

This invention pertains to implantable catheters, and, more particularly, to systems for effecting the stabilization on the skin of a patient of the extracorporeal portion of an implanted vascular access catheter.

2. Background Art

It is now common to use an implanted catheter to repeatedly access the vascular system of a patient and with the catheter perform repeated therapeutic medical activity. Such therapeutic activity could include the intermittent or continuous infusion of medication and fluids, the periodic sampling of blood, or the continuous withdrawal and return of blood for processing outside of the body of the patient. The catheters used in these activities are referred to as vascular access catheters.

Before any therapeutic activity can actually commence, however, the vascular access catheter must be implanted in the body of the patient with the distal tip of the catheter residing at the location in the vascular system at which an intended therapeutic activity is appropriate. Typically, most of the length of an implanted vascular access catheter resides within blood vessels of the vascular system, extending from the distal tip of the catheter to a location in the vascular system at which the catheter, by traversing a puncture or incision formed through a wall of the blood vessel in which the catheter is disposed, enters into the surrounding subcutaneous tissue of the patient. The location at which this occurs is referred to as a venipuncture site. Venipuncture sites are classified on the basis of the position of a venipuncture site in relation to the center of the body of the patient. Central venipuncture sites are those at the superior or inferior vena cava. Midlavicular venipuncture sites are located medial of the shoulder of the patient, but lateral of the subclavian vein. Midline venipuncture sites enter the upper basilic or cephalic veins. The freedom to select among venipuncture sites is most curtailed relative to patients of slight stature, particularly small children and infants.

Proximal of the venipuncture site, the implanted catheter extends through the subcutaneous tissue of the patient to emerge through the skin at a location that is referred to as the skin exit site. Most skin exit sites are chosen as being locations at which the proximal end of the implanted catheter can be easily manipulated by medical personnel. Favored among such locations are the neck, the region about the collar bone, the upper leg, the upper arm, and the forearm.

Occasionally, the skin exit site is somewhat removed from the venipuncture site. Then a significant portion of the length of the implanted catheter must be embedded in the subcutaneous tissue of the patient in a surgically created tunnel that extends from the venipuncture site to the skin exit site. The disposition of a significant portion of the length of an implanted catheter in such a subcutaneous tunnel assists in stabilizing the implanted catheter by resisting sliding movement of the catheter back and forth, internally at the venipuncture site or externally at the skin exit site.

On the other hand, with patients of slight stature and particularly with small children and infants, the skin exit site is frequently located immediately adjacent to the venipuncture site. Under such conditions, the portion of the implanted catheter disposed in subcutaneous tissue is so short as to permit the body of the catheter to slide back and forth across the venipuncture site, as well as in and out of the skin exit site.

The portion of an implanted catheter that resides in a blood vessel of the vascular access system or within subcutaneous tissue is referred to as the implanted portion of that catheter. In all instances, a portion of the proximal end of an implanted catheter must remain outside of the body of the patient. It is this portion of an implanted catheter, from the proximal end thereof to the skin access site, that is referred to as the extracorporeal portion of the implanted catheter.

The extracorporeal portion of an implanted catheter must be capable of being selectively coupled to and uncoupled from the tubing and medical equipment outside the body of the patient that are required for therapeutic activity. Accordingly, the proximal end of virtually all vascular access catheters terminates in a catheter coupling hub that can be secured in fluid communication with such tubing and medical equipment, or can be capped, valved, or clamped closed between periods of actual use.

The repeated manipulation of the extracorporeal portion of an implanted catheter causes wear in the material of the catheter and reduces the reliability of the attachment between the proximal end of the catheter and the catheter coupling hub. In the absence of countermeasures, forces imposed on the extracorporeal portion of an implanted catheter result in motions of the extracorporeal portion of the catheter that cause damage to the catheter. Motion of the extracorporeal portion of an implanted catheter is also communicated to the skin access site, causing various complications depending upon the length of any subcutaneous tunnel in which a portion of the catheter is imbedded. Where such a subcutaneous tunnel is lengthy, motions of the extracorporeal portion of a catheter are relayed directly to the tissue along the subcutaneous tunnel, causing pain and irritation, precluding healing, and leading to infection. These results in turn can necessitate the explanation of the catheter. Where the portion of an implanted catheter extending subcutaneously between the venipuncture site and the skin exit site is short, motions of the extracorporeal portion of the catheter tend to slide the catheter in and out of the vascular system, causing bleeding and likewise leading to infection.

To counteract these undesirable consequences, a variety of measures are undertaken to stabilize the extracorporeal portion of an implanted catheter on the skin of the patient. Tie-down materials, such as bandaging, patches with upstanding anchoring posts, medical adhesive tape, belts, elastic bands, and sutures, are used for this purpose.

To enhance the effectiveness of such tie-down materials, otherwise unnecessary structures are formed on or attached to the catheter coupling hub or the portion of the proximal end of the catheter attached thereto. For example, it is common in the art of catheter implantation to provide one or more flap-like structures that extend laterally from the catheter coupling hub, from the portion of the proximal end of the catheter attached thereto, or from a tubular sleeve that is disposed about either or both of the catheter and the catheter coupling hub. These structures are referred to as stabilization wings.

Even without the assistance of any tie-down materials, a stabilization wing prevents a catheter coupling hub from rolling along the skin of the patient, pivoting about the skin exit site, and twisting the extracorporeal portion of the catheter between the skin exit site and the coupling hub. Sliding motions of a coupling hub on the skin of the patient in directions normal to the length of the catheter are curtailed by the use of tie-down materials applied over or about the coupling hub and against the skin. Tie-down materials also prevent movement of the coupling hub and associated catheter in directions aligned with the length of the catheter, motions that could dislodge the catheter from the skin exit site entirely. Stabilization wings enhance the purchase afforded on the catheter coupling hub by tie-down materials.

A system for coupling an implanted catheter to extracorporeal medical equipment and simultaneously stabilizing the extracorporeal portion of that catheter is complex to design. It is a process that must accommodate a variety of functional needs in an environment involving materials as different as human tissue, bodily fluids, flexible fluid conduits, rigid coupling structures, and various tie-down materials. The extracorporeal portion of an implanted catheter functions as an interface between the environment within the body of the patient at the distal tip of the catheter and extracorporeal medical equipment. At this interface, the patency of tubing, the minimizing of wear, the suppression of exit site infection, the freedom of access by medical personnel, and the inconspicuousness of the extracorporeal portion of the implanted catheter are each desired to be maintained to optimum degrees.

As new classes of materials are developed that are suitable for medical use, the potential of each in relation to existing catheter coupling and stabilization systems is investigated, and the design of such systems evolves accordingly.

Nonetheless, a significant problem in the design of coupling and stabilization systems arises from the contradictory material properties considered desirable among the various components of such systems.

The criteria of suitability for the implanted portion of a catheter that is disposed in the vascular system or the subcutaneous tissue of a patient are dramatically different from the criteria of suitability for the environment outside the body in which the extracorporeal portion of an implanted catheter is disposed and utilized. The implanted portion of a vascular access catheter must be so flexible and soft as to avoid damaging internal tissues and to minimize injury to the cells of the blood. The extracorporeal portion of that same implanted catheter must, by contrast, sustain repeated manipulation and predictable accidental or intentional abuse.

Among the extracorporeal portion of an implantable catheter assembly are components that are hard and entirely inflexible, such as clamps and coupling fixtures that must interact with extracorporeal tubing and medical equipment. In view of the possibility of extended contact by the extracorporeal portion of an implanted catheter with the skin of the patient, contrasting material properties of softness and flexibility suitable for skin contacting applications are also desirable in the extracorporeal interface.

Thus, many desirable material properties are inconsistent with others. As a result, efforts to optimize coupling and stabilization system designs have on occasion used differing classes of materials in various distinct components of the catheter coupling and stabilization system. The tension between the mechanical properties required in the extracorporeal interface for an implanted catheter and the patient comfort properties desirable therein has been resolved only to varying degrees in different systems.

One approach to achieving a marriage of the inconsistent material properties desired in a coupling and stabilization system has been to resort to nonunitary coupling and stabilization systems. Such systems involve some components that embody one set of desired material properties that are assembled in the field by medical personnel with other components that embody a contrasting set of desired material properties. For example, brackets optimizing patient comfort properties are secured to the skin of a patient and used as retainers to stabilize catheter coupling hubs made of tough materials possessed of optimized mechanical properties.

Coupling and stabilization systems configured from components assembled in the field are disadvantaged, however. Individual components can become lost, mismatched components can inadvertently be used together, or important components may never be employed as a result of slipshod practices. Individual components are small and difficult to manipulate, while the maintenance of inventories of a variety of individual interconnecting coupling and stabilization system elements increases institutional overhead.

The selection of structural elements for the extracorporeal interface and the relative positioning of the selected structural elements in a given coupling and stabilization system similarly require design trade-offs that are unlikely to be optimized in any single system.

For example, coupling and stabilization systems that utilize stabilization wings positioned at or adjacent to the catheter coupling hub of the system are effective in precluding movement of the catheter coupling hub. This high level of stability in the catheter coupling hub is obtained, however, at the cost of restricting the ease with which the catheter coupling hub can be manipulated by medical personnel. When stabilization wings in an extracorporeal interface are positioned longitudinally at or close to a catheter coupling hub, the stabilization wings and the catheter coupling hub share relatively similar degrees of freedom. As a consequence, the coupling and uncoupling of extracorporeal tubing and medical devices at the catheter coupling hub are undesirably difficult. Forces imposed on the catheter coupling hub or on the portion of the proximal end of the catheter attached thereto, and motions imparted to either as a result, are communicated directly to the stabilization wings, tending to dislodge the stabilization wings from the skin of the patient. This can be uncomfortable and may lead to tissue irritation at that location. Dislodgment of stabilization wings or a coupling hub from associated tie-down materials or from the skin is likely to lead to catheter damage or catheter explanation.

The positioning of stabilization wings along the proximal end of a catheter distally from the catheter coupling hub produces a different mix of consequences.

Stabilization wings have been longitudinally fixed on the exterior of the extracorporeal portion of a catheter tube at a distance from the catheter coupling hub. When secured to the skin of a patient, the stabilization wings of such systems permit easy access to and use of the catheter coupling hub, because of the flexibility embodied in the material of the catheter between the stabilization wings and the catheter coupling hub. Nonetheless, tortional and axial forces imposed on the catheter coupling hub are still communicated directly to the stabilization wings, as surely as if those stabilization wings were positioned immediately at the catheter coupling hub.

In some coupling and stabilization systems, stabilization wings are attached to the distal end of an elongated sleeve that is in turn secured at the proximal end thereof to the exterior of the catheter coupling hub. The full length of the interior of the sleeve is bonded to the exterior of the catheter tube distal of and adjacent to the coupling hub, producing a composite structure distal of the coupling hub. Such sleeves thicken, and therefore strengthen, the portion of the catheter tube enclosed therein, increasing the durability of the composite structure. Nonetheless, the composite structure tends to exhibit reduced flexibility, impairing intended movements of the catheter coupling hub relative to the stabilization wings. Also, axial forces imposed on the catheter coupling hub are communicated directly to the stabilization wings.

Some of these difficulties may be overcome, but not without foregoing other advantages.

Stabilization wings are, on occasion carried on a sleeve that can be slid along the extracorporeal portion of an implanted catheter and positioned on the skin of the patient at any desired distance from the catheter coupling hub. The securement of such stabilization wings to the skin prevents lateral movement of the portion of the catheter that is between the stabilization wings and the skin exit site. As the sleeve carrying the stabilization wings is not secured in any fixed relation to the catheter or the coupling hub, undesirable longitudinal and rotational movement of the catheter coupling hub relative to the stabilization wings is nonetheless common. Stabilization wings carried on slidable sleeves are susceptible to disposition at improper locations and are thus sensitive to, and in some cases limited in utility by, the skill and talent of specific medical personnel. Slidable sleeves may be overlooked and never used. Some are simply severed from the catheter assembly out of a misplaced desire to simplify the extracorporeal portion of the implanted structure. Longitudinally positionable sleeves carrying stabilization wings are known that completely succumb to this impulse by being manufactured with an axial slit through the sleeve. The sleeve may then be detached at will from the system of which it is supposed to be a component.

It may be realistic in addressing the diverse demands placed on the extracorporeal interface of an implanted catheter to acknowledge that any distinct coupling and stabilization system is advantageous in selected respects and disadvantaged in others.

SUMMARY OF THE INVENTION

Accordingly, one broad objective of the present invention is to facilitate the delivery of medical care by improving the capacity of medical personnel to perform repeated therapeutic medical activity in the vascular system of a patient.

Correspondingly, another objective of the present invention is to simultaneously improve the mechanical reliability and the patient comfort provided by the extracorporeal portion of an implanted vascular catheter.

In this regard, it is an objective of the present invention to provide a catheter coupling and stabilization system that is not sensitive to or limited by the skill and talent of medical personnel, but rather is a failsafe system.

An additional object of the present invention is to optimize tradeoffs in a catheter coupling and stabilization system between the advantages of material toughness and the desirability of ergonomic compatibility.

It is also an object of the present invention to provide such a system from which it is not possible to lose, misplace, or misposition constituent components.

Yet another objective of the present invention is a catheter coupling and stabilization system as described above, that is able to reduce skin irritation and infection at the skin exit site, while yet permitting easy manipulation of the catheter coupling hub of the system by medical personnel.

It is a further object of the present invention to provide a catheter coupling and stabilization system in which forces imposed to a catheter coupling hub and the resulting motions imparted thereto avoid being transmitted directly to structures of the system that are used to secure the extracorporeal portion of the implanted catheter to the skin of a patient.

Another object of the present invention is to reduce the likelihood of bleeding or infection at the skin exit site for an implanted vascular access catheter, thereby to prolong the potential duration of the catheter in an implanted condition.

It is yet another object of the present invention that a catheter coupling system as described above readily communicate to users of the system the size of the catheter with which the system is employed.

Additional objects and advantages of the invention will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by the practice of the invention. The objects and advantages of the invention may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims.

To achieve the foregoing objects, and in accordance with the invention as embodied and broadly described herein, an implantable vascular access catheter is provided that includes a conduit of relatively tough biocompatible material and an elastomeric sleeve suitable for skin contact applications that encircles some part of the extracorporeal portion of the implanted conduit. Typically, the distal end of the conduit is configured as a catheter coupling hub by which to effect mechanical and fluid interactions with extracorporeal medical equipment. A pair of stabilization wings extends laterally from opposite sides of the sleeve at an attachment location that is separated from the catheter coupling hub.

As a result of this spatial separation, and in view of the elastomeric composition of the sleeve, a strain relief region results in the sleeve between the stabilization wings and the location of the catheter coupling hub in the sleeve.

Therefore, according to one aspect of the present invention, a catheter as described above includes resilient means for reducing motion imparted to the skin of the patient by the stabilization wings due to motion imparted to the catheter coupling hub. According to teachings of the present invention, structures performing this function are optimally located between the attachment location on the sleeve for the stabilization wings and the catheter coupling hub that is encircled at least in part by the sleeve.

In accordance with yet another aspect of the present invention, a stabilization sleeve as described above includes an elongated tube having a proximal end, a distal end, and a passageway extending longitudinally between the proximal end and the distal end. The passageway is sized to slideably receive the catheter that is to be used with the stabilization sleeve. A catheter coupling hub receiving socket is included at the proximal end of the tube, and at least the distal end of the catheter coupling hub or the catheter assembly intended to be used with the stabilization sleeve is secured in the receiving socket. The portion of the catheter distal of and adjacent to the catheter coupling hub extends freely through the remainder of the passageway through the stabilization sleeve.

While numerous materials are likely to prove adequate as constituent materials of each respective portion of the cou-

pling and stabilization system, various types of tough polyurethane have been found to be effective for the conduit of the system, while medical grade silicone is the material of choice for the stabilization sleeve.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the manner in which the above-recited and other advantages and objects of the invention are obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered limiting of the scope thereof, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

FIG. **1** is a perspective view of the extracorporeal portion of an implanted vascular access catheter having a coupling and stabilization system that incorporates teachings of the present invention and that is connected thereby to extracorporeal medical tubing;

FIG. **2** is an enlarged perspective view of the extracorporeal portion of the implanted catheter of FIG. **1** with the extracorporeal medical tubing shown in FIG. **1** disconnected therefrom to display the coupling and stabilization system of the implanted catheter in the assembled state thereof,

FIG. **3** is an enlarged, partially disassembled perspective view of the catheter assembly and a first embodiment of a stabilization sleeve of the coupling and stabilization system of FIG. **2**;

FIG. **4** is a plan view in cross section of the stabilization sleeve of FIG. **3** taken along section line **4—4** shown therein;

FIG. **5** is an elevation view in cross section of the stabilization sleeve of FIG. **3** taken along section line **5—5** shown therein;

FIG. **6** is a plan view in cross section of the assembled state of the coupling and stabilization system shown in FIG. **2** taken along section line **6—6** therein;

FIG. **7** is an elevation view in cross section of the assembled state of the coupling and stabilization system shown in FIG. **2** taken along section line **7—7** therein;

FIG. **8** is a transverse elevation view in cross section of the assembled state of the stabilization system shown in FIG. **2** taken along section line **8—8** therein;

FIG. **8A** is a transverse elevation cross section of the assembled state of the stabilization system shown in FIG. **2** taken along section line **8A—8A** appearing in each of FIGS. **6** and **7**;

FIG. **9A** is an enlarged detail of a portion of the coupling and stabilization system shown in FIG. **6**;

FIG. **9B** is an illustration of the interaction of the strain relief features of the coupling and stabilization system of FIG. **9A** with the portion of the catheter enclosed therein under conditions of strain in which the portion of the system in the right of the figure is displaced in a downward direction;

FIG. **9C** is an illustration of the interaction of the strain relief features of the system of FIG. **9A** with the portion of the catheter enclosed therein under conditions of strain in which the portion of the system in the right of the figure is displaced to the right;

FIG. **10A** is a plan view schematic illustration of an initial step in the securement of the extracorporeal portion of a catheter to the skin of a patient using medical adhesive tape and the coupling and stabilization system of FIG. **2**;

FIG. **10B** is a plan view schematic illustration of a second step in the securement of the extracorporeal portion of the catheter of FIG. **10A** to the skin of a patient;

FIG. **10C** is a plan view schematic illustration of a third step in the securement of the extracorporeal portion of the catheter of FIG. **10B** to the skin of a patient;

FIG. **10D** is a plan view schematic illustration of a final step in the securement of the extracorporeal portion of the catheter of FIG. **1** to the skin of a patient;

FIG. **11A** is an enlarged detail of a portion of the coupling and stabilization system shown in FIG. **7**;

FIG. **11B** is an illustration of the interaction of the strain relief features of the system of FIG. **11A** with the portion of the catheter enclosed therein under conditions of strain in which the portion of the system in the right of the figure is displaced in a downward direction;

FIG. **11C** is an illustration of the interaction of the strain relief features of the system of FIG. **11A** with the portion of the catheter enclosed therein under conditions of strain in which the portion of the system in the right of the figure is displaced to the right;

FIG. **12A** is a plan view of a second embodiment of a stabilization sleeve of the type illustrated in FIG. **3**;

FIG. **12B** is a plan view of a third embodiment of a stabilization sleeve of the type illustrated in FIG. **3**;

FIG. **12C** is a plan view of a fourth embodiment of a stabilization sleeve of the type illustrated in FIG. **3**; and

FIG. **12D** is a plan view of a fifth embodiment of a stabilization sleeve of the type illustrated in FIG. **3**.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. **1** illustrates in perspective view the extracorporeal portion of a vascular access catheter **10** implanted in the body of a patient at a skin exit site **12** located on the forearm **14**. The portion of vascular access catheter **10** illustrated in FIG. **1** utilizes a coupling and stabilization system **16** that incorporates teachings of the present invention and that is connected thereby to extracorporeal medical tubing **18**. Coupling and stabilization system **16** is shown by way of example in FIG. **1** as being secured to the skin **20** of forearm **14** by suture ties **22**, although coupling and stabilization system **16** is configured for ready stabilization on the skin of a patient using a plurality of other types of tie-down materials, such as bandaging, patches with upstanding anchoring posts, medical adhesive tape, belts, and elastic bands.

Specific additional features of coupling and stabilization system **16** are illustrated in FIG. **2**, wherein extracorporeal tubing **18** has been disconnected from coupling and stabilization system **16**, revealing male Luer connector threads **24** at the end of coupling and stabilization system **16** opposite skin exit site **12** and the portion of vascular access catheter **10** visible in FIG. **2**. The internal nature of the components of coupling and stabilization system **16** are not immediately apparent from FIG. **2**, but such internal structures will be illustrated and discussed subsequently. It will suffice in relation to FIG. **2** to present an overview of selected features of coupling and stabilization system **16** that can be appreciated through external inspection.

Luer connector threads **24** are formed on a catheter coupling hub **26** that encloses the proximal terminus of a longitudinally extending fluid flow lumen. The distal end of

catheter coupling hub **26**, while not visible in the assembled state of coupling and stabilization system **16** illustrated in FIG. **2**, is secured in an enlarged hub receiving socket **30** that is provided on opposite sides of the exterior thereof with concave finger grips **32**. Distal of hub receiving socket **30**, but separated a distance therefrom, is a pair of laterally extending, coplanar stabilization wings **34** through which suture ties **22** have been stitched to skin **20** of forearm **14**.

According to one aspect of the present invention, coupling and stabilization system **16** is comprised of two classes of materials having selected physical properties that are substantially different. Vascular access catheter **10** and catheter coupling hub **26** are secured to each other interior of the other components of coupling and stabilization system **16** that are visible in FIG. **2**. Together vascular access catheter **10** and catheter coupling hub **26** comprise a catheter assembly **36**. Catheter assembly **36** is comprised of a first class of biocompatible materials that is appropriate for the conditions to which the implanted portion of vascular access catheter **10** is exposed in the cardiovascular system or in the tissues of a patient. The first class of materials must, in addition, be suited to the environment in which the extracorporeal portion of implanted vascular access catheter **10** is disposed and utilized outside the body of the patient. Lumen **28** should thus be enclosed in a conduit of relatively tough biocompatible material that extends from catheter coupling hub **26** through vascular access catheter **10** to the distal end thereof that is not visible in FIG. **2**, but that is disposed at a location in the vascular system of the patient at which repeated therapeutic activity is to be conducted. Various thermoplastic materials are satisfactory for use as such a first class of materials in the fabrication of the components of catheter assembly **36**.

Typically, catheter coupling hub **26** is a very rigid structure comprised of a much harder material than is catheter **10**. Nonetheless, both of these components of catheter assembly **36** can be fabricated from a thermoplastic material, such as polyurethane, provided that the hardness of each respective component is maintained within acceptable ranges through the use of differing types of polyurethane.

Catheter **10** should has a hardness in a range from about 74 Shore A durometer to about 65 Shore D durometer. Most broadly, the hardness of catheter **10** is in a range from about 50 Shore A durometer to about 84 Shore D durometer. It is also acceptable within the scope of the teachings of the present invention to fabricate catheter **10** by coextruding an inner layer that is immediately adjacent to and defining of the lumen in catheter **10** with an outer layer on the exterior thereof that is comprised of a softer material than the inner layer.

Coupling hub **26** should by comparison be generally much harder. For example, coupling hub **26** should have a hardness in a range in excess of 50 Shore D durometer. More narrowly, however, coupling hub **26** will perform adequately with a hardness in a range of from about 80 Shore D durometer to about 84 Shore D durometer. Under appropriate circumstances, materials other than polyurethane can serve adequately as materials from which to fabricate either element of catheter assembly **36**. Such alternative materials include polyvinylchloride, nylon, polyester, castable epoxy, and even metals, such as stainless steel or titanium.

Hub receiving socket **30**, finger grips **32**, and stabilization wings **34** are external features of an elastomeric stabilization sleeve **38**. Stabilization sleeve **38** encircles the distal end of catheter coupling hub **26**, which is not visible in FIG. **2**, and also encircles a portion of the proximal end of vascular access catheter **10** that is adjacent to catheter coupling hub **26** but that is also not visible in FIG. **2**. These portions of catheter assembly **36** do, however, appear in FIG. **3**, in relation to which these portions of catheter assembly **36** are identified by reference characters and discussed in further detail subsequently. In contrast to catheter assembly **36**, stabilization sleeve **38** is comprised of a second class of materials that is soft, flexible, and suitable for skin contacting applications.

Currently, the material of choice for stabilization sleeve **38** is a thermoset material, such as biocompatible silicone. The hardness of stabilization sleeve **38** should be in a broad range of from about 35 Shore A durometer to about 100 Shore A durometer. More specifically, the hardness of stabilization sleeve **38** should be in a range of from about 74 Shore A durometer to about 80 Shore A durometer. The fabrication of stabilization sleeve **38** is not, however, limited to such materials, as the use of polyurethane possessed of appropriate hardness properties is also contemplated for use as stabilization sleeve **38**. In any case, it is recommended that the material of which sleeve **38** is fabricated be a material that can be cleaned using a substance selected from the group comprising alcohol, acetone, and polyethylene glycol.

One of the selected physical properties that may advantageously be made to contrast between catheter assembly **36** and stabilization sleeve **38** is the visual appearance of each. It is possible, for example, to use a single color of material for all sizes of catheter **10** used in a catheter assembly, such as catheter assembly **36**. The material used for the corresponding stabilization sleeve **38** with each different size of catheter may, however, be rendered in a different hue in order to facilitate the ready identification according to a code of colors of the size of the catheter being utilized.

The relationships among the components of coupling and stabilization system **16** are presented with enhanced clarity in FIG. **3**. There, catheter assembly **36**, which is normally permanently secured to stabilization sleeve **38** at catheter coupling hub **26**, only has with vascular access catheter **10** been withdrawn proximally from hub receiving socket **30**, providing a disassembled perspective view of coupling and stabilization system **16**. It is apparent, as a result, that catheter coupling hub **26** is an elongated structure that is secured at the distal end **40** thereof to the proximal end **42** of vascular access catheter **10**. In actuality, catheter coupling hub **26** includes a pair of components. These are a catheter receiving stent **44** and a coupling hub body **46**. Catheter receiving stent **44** surrounds and is attached to the outer surface of the terminus of proximal end **42** of vascular access catheter **10**. Coupling hub body **46** is attached at the distal end **48** thereof to the outer surface **49** of receiving stent **44**. These interconnections can be effected either with an adhesive or, if all constituents of catheter assembly **36** are thermoplastic materials, by heat-induced welding.

The proximal end **50** of coupling hub body **46** carries Luer connector threads **24** that encircle the proximal end **52** of lumen **28**.

FIG. **3** also reveals that the portions of catheter assembly **36** not otherwise visible in the assembled state of coupling and stabilization system **16** illustrated in FIGS. **1** and **2** are in the assembled state of coupling and stabilization **16** encircled by stabilization sleeve **38**. According to one aspect of the present invention, stabilization sleeve **38** is an elongated tube that has a distal end **54**, a proximal end **56**, and a passageway **58** extending longitudinally therebetween. Passageway **58** is so sized as to slideably receive catheter **10**,

but the minimum diameter of passageway **58** is less than the maximum outer diameter of catheter coupling hub **26**. The inner diameter of passageway **58** in stabilization sleeve **38** at proximal end **56** thereof corresponds generally in size to the exterior of proximal end **50** of coupling hub body **46**. A generally cylindrical hollow **59** is formed within hub receiving socket **30** capable of enclosing the full length of catheter assembly **36** other than the portion thereof that carries Luer connector threads **24**. As a result, in the assembled state of coupling and stabilization system **16**, distal end **48** of coupling hub body **46** each made, for example, of polyurethane materials abuts a portion of the interior of stabilization sleeve **38**, while vascular access catheter **10** having a much smaller diameter than the outer diameter of coupling hub body **46** is slideably disposed in the balance of passageway **58** in stabilization sleeve **38**.

Other features of the exterior of stabilization sleeve **38** should receive mention relative to FIG. **3**. According to an aspect of the present invention, the exterior of a sleeve, such as stabilization sleeve **38**, includes attachment means for securing the sleeve at a predetermined position and in a predetermined orientation on the skin of a patient. As shown in FIG. **3**, by way of example of structure capable of performing the function of such an attachment means are a pair of stabilization wings **34**.

Each of stabilization wings **34** can be seen to comprise a planar structure that extends laterally from opposite sides of stabilization sleeve **38** at an attachment location **60**. While the configuration of stabilization wings **34** will be explored in greater detail subsequently, it can be observed that a suture recess **62** is formed in upper surface **64** of each of stabilization wings **34**. At suture recess **62**, the thickness of stabilization wings **34** is a minimum, thereby to facilitate, if desired, the stitching of coupling and stabilization system **16** to the skin of the patient using suture ties **22** in the manner shown in FIGS. **1** and **2**. Stabilization wings **34** and stabilization sleeve **38** may advantageously be integrally formed of a single material.

As attachment location **60** is distanced longitudinally along stabilization sleeve **38** from hub receiving socket **30**, a strain relief region **66** is formed in stabilization sleeve **38** intermediate attachment location **60** and hub receiving socket **30**. Strain relief region **66** of stabilization sleeve **38** has in various embodiments thereof a length greater than 0.32 inches. In other embodiments, however, the length of strain relief region **66** has been greater than only 0.20 inches and at the very least greater than 0.12 inches. A frustoconical strain relief nose **68** is located on stabilization sleeve **38** distal of attachment location **60**.

The interior structure of stabilization sleeve **38** is illustrated in cross section in FIG. **4**. There, each of strain relief nose **68**, attachment location **60**, strain relief region **66**, and hub receiving socket **30** can be correlated with corresponding interior structures of stabilization sleeve **38** along the length of passageway **58**.

At proximal end **56** of stabilization sleeve **38**, proximal entryway **70** of passageway **58** affords access to hollow **59** within hub receiving socket **30**. Hollow **59** includes a generally large diameter cylindrical region **72** at proximal entryway **70**, a smaller diameter cylindrical region **74** at the opposite distal end of hollow **59**, and a frustoconical medial section **76** therebetween. A yet smaller diameter, two-stage distal portion **78** of passageway **58** extends from cylindrical region **74** of hollow **59** to the open distal end **54** of stabilization sleeve **38** at the apex of strain relief nose **68**. Distal portion **78** of passageway **58** includes a larger bore section **80** that passes through attachment location **60** and strain relief region **66**, as well as a small bore region **82** that extends through strain relief nose **68**. Although small bore region **82** of distal portion **78** of passageway **58** has the smallest inner diameter of any component of passageway **58**, the inner diameter of small bore region **82** is nonetheless sufficiently large to slideably house vascular access catheter **10** therein.

On the other hand, it is in hollow **59**, and against the distal end wall **84** of cylindrical region **74** in particular, that receiving stent **44** of catheter coupling hub **26** abuttingly engages a structure in passageway **58** in the assembled condition of coupling and stabilization system **16**. Significantly, according to one aspect of the present invention, stabilization sleeve **38** is affixed to catheter assembly **36** only at hollow **59** using, by way of example, a room temperature vulcanizing silicone rubber adhesive. The portion of catheter assembly **36** distal of hollow **59** is slideably disposed in distal portion **78** of passageway **58**.

One aspect of the configuration of stabilization sleeve **38** is best addressed relative to the elevation cross section of stabilization sleeve **38** shown in FIG. **5**. There, at attachment location **60**, the lower patient contact surfaces **86** of stabilization wings **34** can be seen. Proximal of attachment location **60**, the exterior of stabilization sleeve **38** in the vicinity of hub receiving socket **30** is correspondingly formed into a generally planar skin contact surface **88** that is disposed in a coplanar relationship with patient contact surface **86** on the same side of stabilization sleeve **38** therewith. The orientation of the common plane defined by patient contact surface **86** and skin contact surface **88** is such that when patient contact surface **86** and skin contact surface **88** engage the skin S of a patient, longitudinal axis L_{38} of stabilization sleeve **38** is elevated relative to that common plane at an elevation angle A. In so doing, it is intended according to teachings of the present invention that the elastomeric nature of the material from which stabilization sleeve **38** is comprised will permit strain relief nose **68** to be displaced upwardly in a direction shown in FIG. **5** by arrow F, so that the exterior of strain relief nose **68** on the same side of stabilization sleeve **38** as patient contact surface **86** and skin contact surface **88** will become coplanar therewith, resting on skin S of the patient in the manner shown, for example in FIG. **7**, subsequently.

FIG. **6** illustrates the relationship between the exterior features of catheter assembly **36** and the interior walls of passageway **58**. As illustrated there, receiving stent **44** encircles the exterior of vascular access catheter **10**, while coupling hub body **46** is attached to the exterior of receiving stent **44**. Together, these elements comprise catheter assembly **36**. Lumen **28** extending longitudinally through catheter assembly **36** includes catheter lumen **90** of vascular access catheter **10** and enlarged proximal terminus **92** at proximal end **50** of coupling hub body **46**.

The generalized structural elements of stabilization wings **34** are best investigated in relation to the depictions in FIG. **6**. There, each of stabilization wings **34** can be seen to comprise an anchor root **96** that is secured directly to attachment location **60**. The width of anchor root **96** is the extent of anchor root **96** measured parallel to longitudinal access L_{38} of stabilization sleeve **38**. An anchor wing **98** is secured to the end of anchor root **96** remote from stabilization sleeve **38**. The width of anchor wing **98** is also measured parallel to longitudinal axis L_{38} of stabilization sleeve **38**. Anchor wing **98** is bounded by a trailing edge **100** oriented toward hub receiving socket **30**, a leading edge **102** on the opposite side of anchor wing **98** from trailing edge **100**, and

a tip **104** extending between leading edge **102** and trailing edge **100** remote from stabilization sleeve **38**. In the embodiment of stabilization wing **34** illustrated in FIG. **6**, trailing edge **100** and tip **104** are slightly convex, while leading edge **102** is linear, trailing edge **100** is oriented at an acute angle A_{100p} to longitudinal axis L_{38} of stabilization sleeve **38** distal of attachment location **60**, and leading edge **102** is oriented at an acute angle A_{102p} to longitudinal axis L_{38} of stabilization sleeve **38** proximal of attachment location **60**. A strain relief region extension notch **106** is formed in trailing edge **100** of stabilization wing **34**, thus causing the width of anchor root **96** to be less than the width of anchor wing **98**.

FIG. **7** illustrates many of the same structures already discussed in relation to FIG. **6**. On the left side of FIG. **7**, however, enabled by the resiliency thereof, strain relief nose **68** has been displaced in a direction illustrated by arrow F, so that the exterior of strain relief nose **68** on the same side of stabilization sleeve **38** as patient contact surface **86** and skin contact surface **88** rests in a coplanar relationship therewith on the skin S of a patient. While catheter coupling hub **26** is fixedly engaged within hub receiving socket **30** of stabilization sleeve **38**, catheter **10** distal of and adjacent to catheter coupling hub **26** extends slideably through distal portion **78** of passageway **58**. As a result, catheter **10** at strain relief nose **68** is not displaced in the direction of arrow F or to any similar degree as strain relief nose **68**. Catheter **10** comes to be disposed within small bore region **82** and large bore region **80** of distal portion **78** of passageway **58** in a nonconcentric relationship. The flexibility of the material of which stabilization sleeve **38** is comprised in combination with the slidable disposition of vascular access catheter **10** within distal portion **78** of passageway **58** in stabilization sleeve **38** permits strain relief nose **68** and, to an extent, attachment location **60** to afford relief to catheter **10** from lateral types of bending strain.

As a result of the configuration of the portion of stabilization sleeve **38** proximal of attachment location **60**, the longitudinal axis L_{38} of stabilization sleeve **38** and the longitudinal axis of lumen **28** at the proximal end of catheter assembly **36** are disposed at an inclination angle A to the skin S of the patient.

According to one aspect of the present invention, in a catheter coupling and stabilization system, such as coupling and stabilization system **16**, cooperating alignment means are provided for facilitating and stabilizing a predetermined rotational relationship between a stabilization sleeve of that system and the catheter coupling hub of the catheter assembly associated therewith. By way of example and not limitation, as illustrated to best advantage in FIG. **8**, the exterior of catheter coupling hub **26** is provided with an upstanding, longitudinally extending alignment rib **110** that is received in correspondingly longitudinally aligned alignment rib receiving slot **112** formed in the wall of passageway **58** at cylindrical region **72** of hollow **59**. Together, alignment rib **110** and alignment rib receiving slot **112** function as a key and keyway system **114**.

FIGS. **9A–9C** depict the effects on the relationship of structures in the interior of coupling and stabilization system **16** resulting when stabilization wings **34** are secured to the skin of a patient and movement parallel to the skin is imparted to catheter coupling hub **26**.

FIG. **9A** is an enlarged detail of a portion of coupling and stabilization system **16** illustrated in FIG. **6**. Salutary effects of specific aspects of coupling and stabilization system **16** will be explored. Stabilization sleeve **38** is comprised of an elastomeric material. Catheter **10** is slideably disposed in distal portion **78** of passageway **58** in stabilization sleeve **38**. Receiving stent **44** is permanently secured in hub receiving socket **30**. Strain relief region **66** is advantageously positioned between attachment location **60** and the distal portion of catheter coupling hub **26**. According to an aspect of the present invention a sleeve, such as stabilization sleeve **38**, includes resilient means for reducing motion imparted to the skin of a patient by stabilization wings, such as stabilization wings **34**, due to motion imparted to a catheter coupling hub, such as catheter coupling hub **26**. As shown in FIG. **9A**, an example of structure capable of performing the function of such a resilient means is strain relief region **66**.

In FIG. **9B**, a force has been applied to hub receiving socket **30** that has displaced hub receiving socket **30** and receiving stent **44** therein downwardly from the original position thereof indicated in phantom in a direction indicated by arrow R. The ability to freely pivot hub receiving socket **30** in this manner contributes to the ease with which extracorporeal tubing and medical equipment can be engaged to the proximal end of a catheter incorporating a coupling and stabilization system according to the present invention. The strain of this type of displacement of hub receiving socket **30** is not, however, communicated directly to the skin S of the patient at stabilization wings **34**.

Instead, strain relief region **66** assumes a twisted configuration **66A**, and vascular access catheter **10** is drawn along distal portion **78** of passageway **58** in the direction indicated by arrow X. The movement of hub receiving socket **30** as indicated by arrow R does not produce corresponding movement in stabilization wings **34** or in the skin of the patient to which stabilization wings **34** are attached. Furthermore, upon the release of whatever force produced the movement of hub receiving socket **30** indicated by arrow R, the resiliency of strain relief region **66** will restore hub receiving socket **30** to the original position thereof indicated in phantom in FIG. **9B**. Catheter **10** will correspondingly return longitudinally in a direction opposite that indicated by arrow X and resume the original position thereof, both in and out of the vascular system.

Similar benefits occur in relation to longitudinal displacements of hub receiving socket **30** with receiving stent **44** fixed therein. Such a situation is illustrated in FIG. **9C**. There, a force applied to hub receiving socket **30** has displaced hub receiving socket **30** in the direction indicated by arrow L. Instead of correspondingly displacing stabilization wings **34** or the skin of the patient to which stabilization wings **34** are attached, strain relief region **66** becomes distended into an elongated shape **66B**, and vascular access catheter **10** slides freely within distal portion **78** of passageway **58**. The strain imposed on hub receiving socket **30** is in effect dissipated or attenuated by strain relief region **66** of stabilization sleeve **38**.

Strain relief region **66** affords other advantages as will be discussed in relation to FIGS. **10–10D**. These figures illustrate steps in the securement of the extracorporeal portion of a catheter embodying teachings of the present invention to the skin of a patient using medical adhesive tape **120** and coupling and stabilization system **16**. The positioning of attachment location **60** for stabilization wings **34** at a distance from hub receiving socket **30** and thus catheter coupling hub **26** permits medical adhesive tape **120** to be used with optimum effectiveness.

Medical adhesive tape **120** has an adhesive side **122** that is shaded in the figures and a nonadhesive side **124** that is free of shading.

In FIG. 10A, the first step of this procedure is illustrated. Adhesive side 122 of medical adhesive tape 120 is disposed against the lower side of coupling and stabilization system 16 at strain relief region 66. The free ends 126, 128 of medical adhesive tape 120 extend laterally beyond tips 100 of stabilization sleeves 38, and trailing edges 104 of stabilization sleeves 38 overlie adhesive side 122 of medical adhesive tape 120.

This latter situation is then altered in the manner illustrated in FIG. 10B. Free ends 126, 128 of medical adhesive tape 120 are pivoted at strain relief region 66 about and over trailing edges 100 of stabilization wings 34. Medical adhesive tape 120 thus continues unwrinkled to occupy strain relief region 66 between attachment location 60 and hub receiving socket 30.

As illustrated in FIG. 10C, free end 126 of medical adhesive tape 120 is next crossed over strain relief region 66 and the upper surface 62 of stabilization wing 34 on the opposite side of stabilization sleeve 38.

Finally, the same procedure is undertaken with relation to free end 128 of medical adhesive 120. The results are illustrated in FIG. 1 OD. Through the use of medical adhesive tape 120 as a tie-down material, coupling and stabilization system 16 is firmly secured at attachment location 60 to the skin of the patient. Still, substantial freedom of movement is permitted in hub receiving socket 30 and catheter coupling hub 26, as was discussed relative to FIGS. 9B and 9C. The length of strain relief region 66 contributes to this positive result, as does the slidable disposition of catheter 10 through the portion of stabilization sleeve 38 distal of catheter coupling hub 26.

FIGS. 11A–11C depict the effects on the relationship of structures in the interior of coupling and stabilization system 16 as a result of other types of movements than those illustrated in FIGS. 9B and 9C are imparted to catheter coupling hub 26 when stabilization wings 34 are secured to the skin of a patient as, for example, in the manner taught in FIGS. 10A–10D.

FIG. 11A is an enlarged detail of a portion of coupling and stabilization system 16 illustrated in FIG. 7.

In FIG. 11B, a force has been applied to hub receiving socket 30 that has displaced hub receiving socket 30 and receiving stent 44 upwardly in a direction indicated by arrow T from the original position thereof shown in FIG. 11A and indicated in FIG. 11B in phantom. The ability to freely pivot hub receiving socket 30 in this manner contributes to the ease with which extracorporeal tubing and medical equipment can be engaged to the proximal end of a catheter incorporating a coupling and stabilization system according to the present invention. The strain of this type of displacement of hub receiving socket 30 is not, however, communicated directly to the skin S of the patient at stabilization wings 34.

Instead, strain relief region 66 assumes a twisted configuration 66C, and vascular access catheter 10 is drawn along distal portion 78 of passageway 58 in the direction indicated by arrow J. The movement of hub receiving socket 30 as indicated by arrow T does not produce 10 corresponding movements in stabilization wings 34 or in the skin of the patient to which stabilization wings 34 are attached. Furthermore, upon the release of whatever force produced the movement of hub receiving socket 30 indicated by arrow T, the resiliency of strain relief region 66 restores hub receiving socket 30 to the original position thereof indicated in phantom in FIG. 11B. Catheter 10 will correspondingly return longitudinally in the direction opposite that indicated by arrow J and resume the original position thereof, both in and out of the vascular system.

Similar benefits occur in relation to longitudinal lateral displacement of hub receiving socket 30 with receiving stent 44 fixed therein. Such a situation is illustrated in FIG. 11C. There, a force applied to hub receiving socket 30 has displaced hub receiving socket 30 in the direction indicated by arrow M. Instead of correspondingly displacing stabilization wings 34 or the skin of the patient to which stabilization wings 34 are attached, strain relief region 66 becomes distended into an elongated shape 66D, and vascular access catheter 10 slides freely within distal portion 78 of passageway 58. The strain imposed on hub receiving socket 30 is in effect dissipated or intenuated by strain relief region 66 of stabilization sleeve 38..

FIGS. 12A–12D illustrate a number of alternative embodiments of catheter coupling and stabilization systems that incorporate teachings of the present invention and exhibits a variety of configurations of the stabilization sleeves utilized with such systems.

In FIG. 12A, a stabilization sleeve 38A is illustrated. A pair of stabilization wings 140 projects laterally from opposite sides of stabilization sleeve 38A at attachment location 60. Stabilization wing 140 has an anchor root 142 and an anchor wing 144. Trailing edge 146 of stabilization wing 140 is substantially linear and is oriented at an acute angle A_{146p} to longitudinal axis L_{38A} of stabilization sleeve 38A being oriented by contrast at an acute angle A_{148d} to longitudinal axis L_{38A} distal of attachment location 60 proximal of attachment location 60. Leading edge 148 of stabilization wing 140 is substantially straight adjacent to stabilization sleeve 38A, but curving broadly at the end thereof remote from stabilization sleeve 38A to tangentially intersect tip 150 of stabilization wing 150. Tip 104, which is substantially linear, is disposed in a substantially parallel arrangement with longitudinal axis L_{38A} of stabilization sleeve 38A. A notch 152 in trailing edge 146 of stabilization wing 140 results in root 142 of stabilization wing 140 being narrower than anchor wing 144.

In FIG. 12B, yet another stabilization sleeve 3 8B is illustrated. A pair of stabilization wings 154 projects laterally from opposite sides of stabilization sleeve 38B at attachment location 60. Stabilization wing 154 is comprised of an anchor root 156 and an anchor wing 158. Trailing edge 160 of stabilization wing 154 is substantially linear, but is oriented at an acute angle A_{160d} to longitudinal axis L_{38B} of stabilization sleeve 38B distal of attachment location 60. Leading edge 162 of stabilization wing 154 is concave and oriented generally at an acute angle A_{162p} to longitudinal axis L_{38B} of stabilization sleeve 38B proximal of attachment location 60. Tip 164 of stabilization sleeve 154 is linear and disposed at an acute angle with longitudinal axis L_{38B} of stabilization sleeve 38B proximal of attachment location 60. A notch 166 is formed in trailing edge 160 of stabilization wing 154 adjacent to stabilization sleeve 38B.

In FIG. 12C, a stabilization sleeve 38C is illustrated. A pair of stabilization wings 170 project laterally from opposite sides of stabilization sleeve 38C at attachment location 60. Stabilization wing 170 includes an anchor root 172 and an anchor wing 174. Both trailing edge 176 and leading edge 178 of stabilization wing 170 are substantially linear and are oriented perpendicular to longitudinal axis L_{38C} of stabilization sleeve 3 8C. Accordingly, trailing edge 176 and leading edge 178 are parallel, and anchor root 172 has a width that is equal to the width of anchor wing 174. Tip 180 of stabilization wing 170 is substantially linear and is

oriented substantially parallel to longitudinal axis L_{38C} of stabilization sleeve **38**C.

In FIG. **12**D, a stabilization sleeve **38**D is illustrated. A pair of stabilization wings **182** projects laterally from opposite sides of stabilization sleeve **38**D at attachment location **60**. Each of stabilization wings **182** includes an anchor root **184** and an anchor wing **186**. Both of trailing edge **188** and leading edge **190** of stabilization wing **182** are substantially linear, and both are oriented at an acute angle to longitudinal axis L_{38D} of stabilization sleeve **38**D proximal of attachment location **60**. Trailing edge **188** thusly forms an acute angle A_{188d} with that portion of longitudinal axis L_{38D} and leading edge **190** does so at an acute angle A_{190d}. Tip **192** of stabilization sleeve **182** is convex. Due to the relative orientation of each of trailing edge **188** and leading edge **190**, however, the width of anchor root **184** is actually greater than the width of any portion of anchor wing **186**.

The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. An implantable vascular access catheter comprising:

a. a conduit of relatively tough biocompatible material enclosing a longitudinally extending fluid flow lumen, said conduit having a distal end configured as an elongated flexible catheter for disposition in the vascular system of a patient and a proximal end configured as a catheter coupling hub by which to effect mechanical and fluid interaction with extracorporeal medical equipment;

b. an elastomeric sleeve suitable for skin contact applications encircling the distal end of said catheter coupling hub and a portion of said conduit distal of and adjacent to said distal end of said catheter coupling hub;

c. a pair of stabilization wings extending laterally from said sleeve distal of said distal end of said catheter coupling hub; and

d. resilient means between said distal end of said catheter coupling hub and said stabilization wings for reducing motion imparted to the skin of a patient through said stabilization wings due to motion of said catheter coupling hub, when said stabilization wings are secured to the skin of a patient.

2. A catheter as recited in claim **1**, wherein said sleeve is attached to said conduit exclusively at said catheter coupling hub.

3. A catheter as recited in claim **2**, wherein said portion of said conduit distal of and adjacent to said distal end of said catheter coupling hub extends slidably through said sleeve.

4. A catheter as recited in claim **1**, wherein said portion of said conduit distal of and adjacent to said distal end of catheter coupling hub extends slidably through said sleeve.

5. A catheter as recited in claim **1**, wherein the hardness of said catheter coupling hub is greater than the hardness of said conduit.

6. A catheter as recited in claim **1**, wherein said catheter coupling hub is comprised of polyurethane.

7. A catheter as recited in claim **1**, wherein said sleeve comprises silicone.

8. A catheter as recited in claim **1**, wherein:

a. said stabilization wings are generally coplanar, each of said stabilization wings having an upper surface and a lower patient contact surface on the opposite side of each of said stabilization wings therefrom;

b. the exterior of said sleeve proximally of said stabilization wings is formed into a generally planar skin contact surface disposed on the same side of said sleeve as said patient contact surfaces of said stabilization wings; and

c. said sleeve at and proximal of said stabilization wings is so configured that when said patient contact surfaces of said stabilization wings and said skin contact surface of said sleeve engage the skin of a patient, the longitudinal axis of said conduit at said proximal end thereof is elevated at an angle to the skin of the patient.

9. A catheter as recited in claim **1**, wherein said stabilization wings and said sleeve are integrally formed of a single material.

10. A catheter as recited in claim **1**, wherein said resilient means comprises a strain relief region of said sleeve.

11. A catheter coupling and stabilization system for the extracorporeal portion of an implant able catheter, said system comprising:

a. a catheter assembly comprised of a first class of materials, said catheter assembly comprising:

i. an elongated flexible catheter having a proximal end and a distal end; and

ii. a catheter coupling hub, the distal end of said catheter coupling hub being secured to said proximal end of said catheter; and

b. a stabilization sleeve encircling said distal end of said catheter coupling hub and a portion of said proximal end of said catheter immediately adjacent thereto, said stabilization sleeve having a passageway extending longitudinally therethrough, said distal end of said catheter coupling hub being secured in the proximal end of said passageway with said portion of said proximal end of said catheter immediately adjacent thereto extending therefrom through said passageway, said stabilization sleeve being comprised of a second class of materials having selected physical properties substantially different from corresponding selected physical properties of said first class of materials, and said stabilization sleeve comprising:

i. a pair of stabilization wings extending from opposite sides of said stabilization sleeve distal of said distal end of said catheter coupling hub; and

ii. a strain relief region between said catheter coupling hub and said stabilization wings, movement of said catheter coupling hub relative to said stabilization wings being facilitated by said strain relief region when said stabilization wings are secured to the skin of a patient.

12. A system as recited in claim **11**, wherein said first class of materials comprises thermoplastic materials that are durable relative to conditions to which the implanted portion of a cardiovascular access catheter is exposed in the cardiovascular system or the tissues of a patient and relative to the environment in which the extracorporeal portion of an implanted catheter is disposed and utilized.

13. A system as recited in claim **12**, wherein said first class of materials comprises polyurethane materials.

14. A system as recited in claim **13**, wherein:

a. said catheter is comprised of a first polyurethane material; and

b. said catheter coupling hub is comprised of a second polyurethane material, said first polyurethane material being softer than said second polyurethane material.

15. A system as recited in claim **11** wherein said second class of materials comprises soft, flexible materials suitable for skin contacting applications.

16. A system as recited in claim 15, wherein said second class of materials comprises thermoset materials.

17. A system as recited in claim 16 wherein said second class of materials comprises biocompatible silicone materials.

18. A system as recited in claim 11, wherein said stabilization sleeve further comprises:

a. an elongated tube having proximal and distal ends, said passageway of said stabilization sleeve extending longitudinally therebetween; and

b. a hub receiving socket formed from said passageway at said proximal end of said tube, said distal end of said catheter coupling hub being secured in said hub receiving socket, said stabilization wings extending laterally from opposite sides of said tube distal of said hub receiving socket.

19. A system as recited in claim 18, wherein the wall of said passageway at said hub receiving socket and the exterior of said catheter coupling hub are provided with cooperating alignment means for facilitating and stabilizing a predetermined rotational relationship between said stabilization sleeve and said catheter coupling hub, when said distal end of said catheter coupling hub is secured in said hub receiving socket.

20. A system as recited in claim 19, wherein said alignment means comprises:

a. an elongated alignment rib upstanding on the exterior of said catheter coupling hub, said alignment rib being oriented generally parallel to the longitudinal axis of said catheter assembly; and

b. an alignment rib receiving slot formed in said wall of said hub receiving socket, said receiving slot being oriented generally parallel to the longitudinal axis of said stabilization sleeve.

21. A system as recited in claim 18, wherein radially opposed finger grips are provided on the exterior of said tube at said hub receiving socket.

22. A system as recited in claim 18, further comprising a strain relief nose located distal of said attachment location.

23. A system as recited in claim 22, wherein the diameter of said passageway at said strain relief nose is greater than or equal to the outer diameter of said catheter.

24. A system as recited in claim 22, wherein the exterior of said strain relief nose is frustoconical.

25. A system as recited in claim 18, wherein each of said stabilization wings is provided with a suture recess at which the thickness of each respective of said stabilization wings is a minimum.

26. A system as recited in claim 18, wherein a strain relief region extension notch is formed in the edge of each of said stabilization wings adjacent to said strain relief region.

27. A system as recited in claim 11, wherein said catheter coupling hub comprises:

a. a catheter receiving stent encircling the outer surface of said proximal end of said catheter; and

b. a hub body encircling the outer surface of said receiving stent.

28. A system as recited in claim 27, wherein said receiving stent is attached to said proximal end of said catheter and to said catheter coupling hub with an adhesive.

29. A system as recited in claim 27, wherein said receiving stent is welded to said proximal end of said catheter and to said catheter coupling hub.

30. A system as recited in claim 11, wherein:

a said first class of materials comprises hard polyurethane materials, and

b. said second class of materials comprises soft polyurethane materials.

31. A system as recited in claim 30, wherein:

a. said catheter is comprised of a first hard polyurethane material; and

b. said catheter coupling hub is comprised of a second hard polyurethane material, said first hard polyurethane material being softer than said second hard polyurethane material.

32. A system as recited in claim 11, wherein said first class of materials comprises castable epoxy materials.

33. A system as recited in claim 11, wherein:

a. said first class of materials comprises polyurethane materials; and

b. said second class of materials comprises biocompatible silicone materials.

34. A system as recited in claim 11, wherein each of said stabilization wings comprises:

a. a trailing edge oriented toward the proximal end of said stabilization sleeve; and

b. a notch formed in said trailing edge of each of said stabilization wings adjacent said stabilization sleeve.

35. A catheter coupling and stabilization system for the extracorporeal portion of an implantable catheter, said system comprising:

a. a catheter having a proximal end and a distal end;

b. a catheter coupling hub, the distal end of said catheter coupling hub being secured to said proximal end of said catheter; and

c. a stabilization sleeve encircling said distal end of said catheter coupling hub and a portion of said proximal end of said catheter immediately adjacent thereto, said stabilization sleeve comprising:

i. an elongated tube having a proximal end, a distal end, and a passageway extending longitudinally therebetween, said distal end of said catheter coupling hub being secured in said passageway at said proximal end of said tube;

ii. attachment means for securing said tube at a predetermined position and in a predetermined orientation to the skin of a patient, said attachment means being located on the exterior of said tube distal of said catheter coupling hub; and

iii. a strain relief region between said catheter coupling hub and said attachment means, movement of said catheter coupling hub relative to said attachment means being facilitated by said strain relief region.

36. A system as recited in claim 35, wherein said attachment means comprises a pair of stabilization wings extending laterally from said tube.

37. A system as recited in claim 35, wherein said attachment means comprises a planar stabilization wing extending laterally from said tube and being disposed generally parallel to the longitudinal axis of said tube, said stabilization wing comprising:

a. a leading edge oriented toward said distal end of said tube;

b. a trailing edge oriented toward said proximal end of said tube;

c. a tip extending between said leading edge and said trailing edge remote from said tube; and

d. a notch formed through said trailing edge of said stabilization wing adjacent said tube.

38. A system as recited in claim 35, wherein said catheter is a single lumen catheter.

* * * * *

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United States Patent [19]

Cox et al.

[11] Patent Number: 5,579,765

[45] Date f Patent: Dec. 3, 1996

[54] **MONITOR TO DETECT BLEEDING**

[76] Inventors: **Danny L. Cox**, 2616 E. Hills Dr., Moore, Okla. 73160; **Bradley J. Bush**, 717 Highway Pky., Norman, Okla. 73069

[21] Appl. No.: **452,987**

[22] Filed: **May 30, 1995**

[51] **Int. Cl.**[6] **A61B 5/00**

[52] **U.S. Cl.** **128/638**; 128/630; 128/734

[58] **Field of Search** 128/630, 638–39, 128/734

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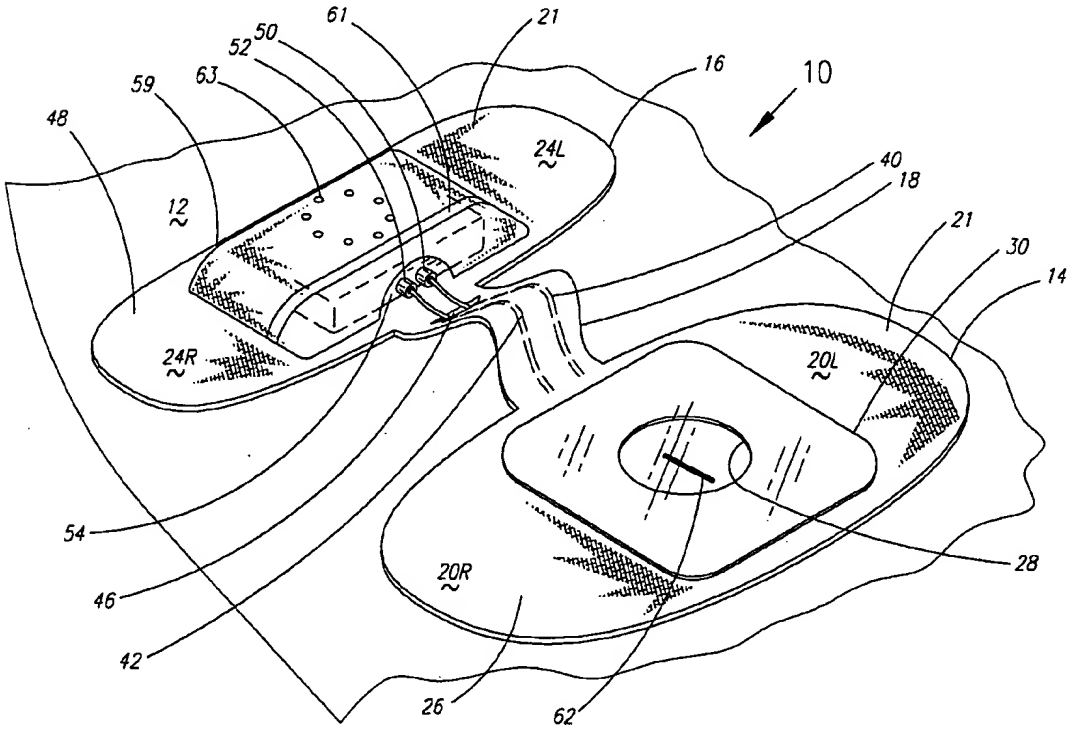
Primary Examiner—Angela D. Sykes
Assistant Examiner—Ryan Carter
Attorney, Agent, or Firm—Molly D. McKay, P.C.

[57] **ABSTRACT**

A monitor for detecting external bleeding from a puncture site on a patient. The monitor is provided with a self-sticking bandage portion on one end connected by means of a flexible connecting strip to a self-sticking holder portion on an opposite end. The bandage portion is applied so the puncture site is visible through a transparent window provided over a central opening in the bandage portion. A pair of spaced apart wires encircles the central opening, extends across the connecting strip and removably secures to a portable alarm device containing a battery and alarm connected in series by means of the wires. When the puncture site hemorrhages, blood contacts the wires, allowing electrical current to flow between the wires via the electrically conductive blood and thus supplying electricity to the alarm in order to activate it.

12 Claims, 3 Drawing Sheets



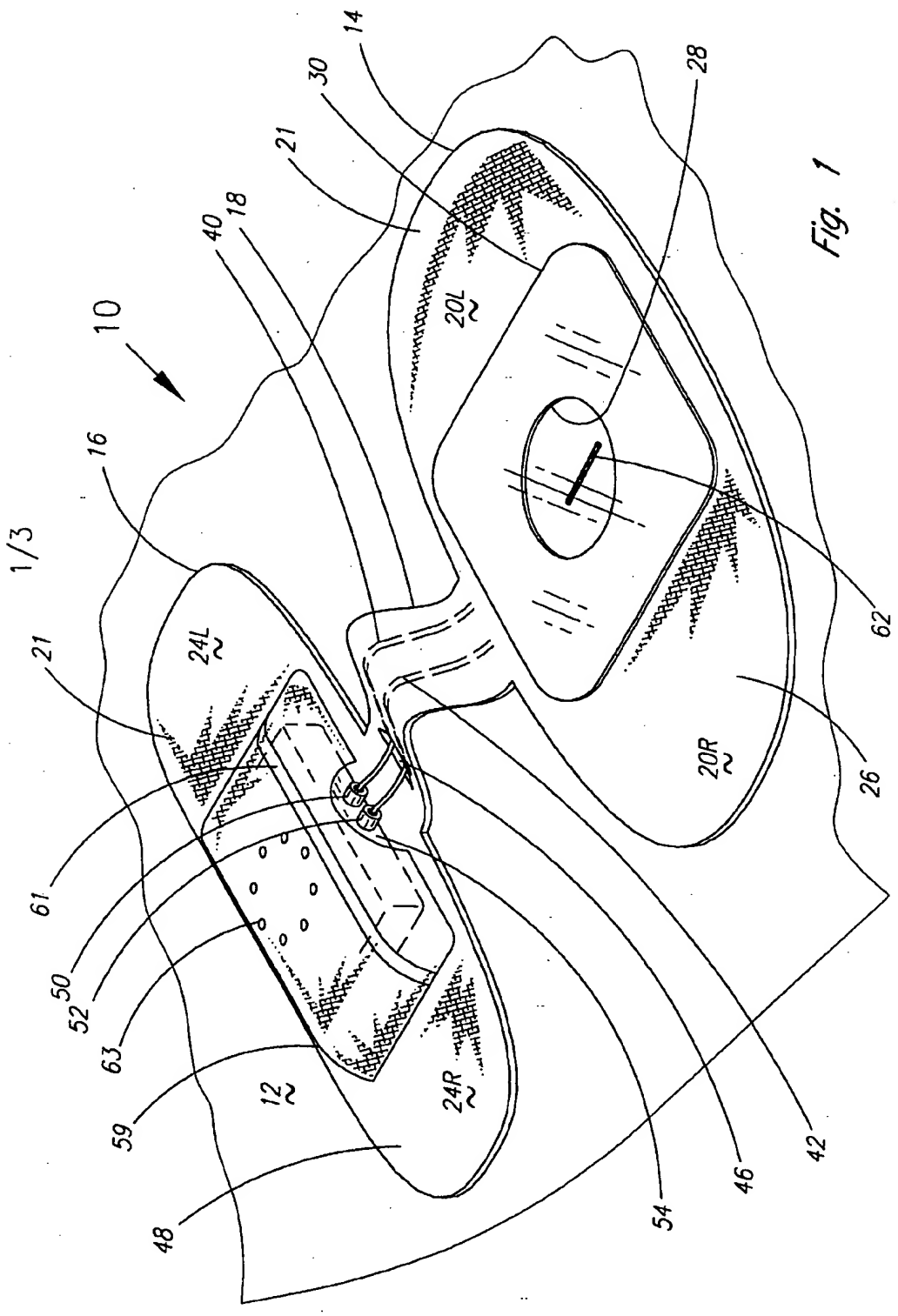

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Fig. 1

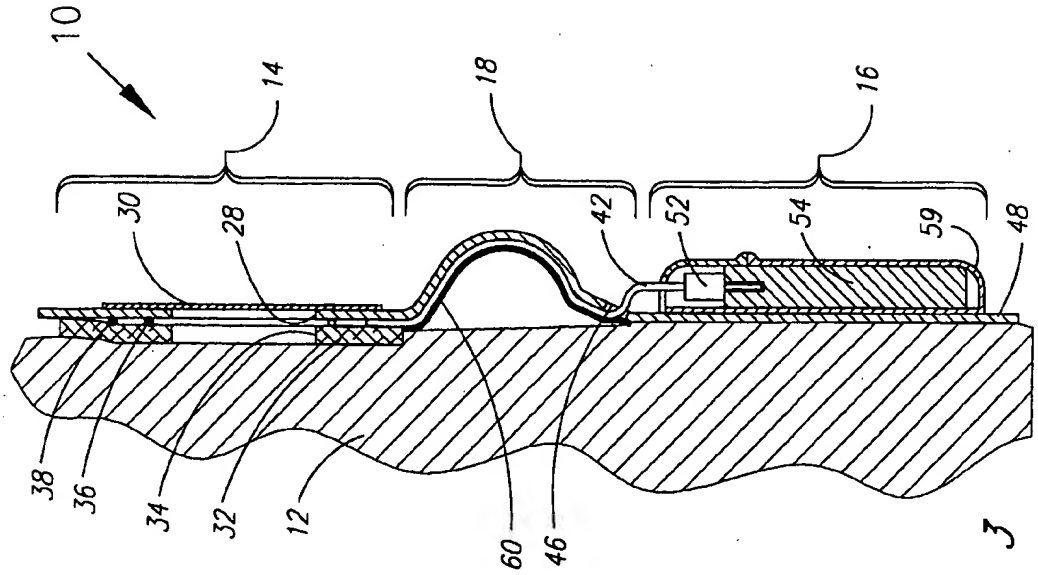
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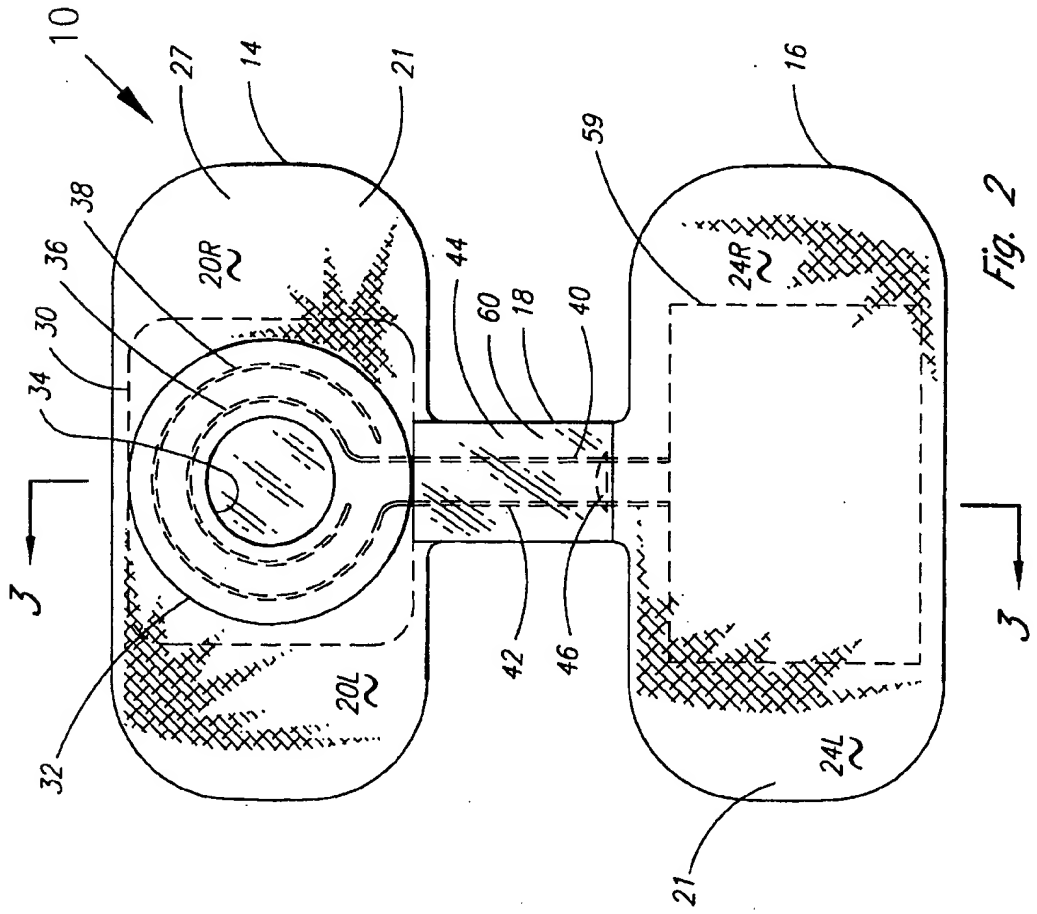
Fig. 3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32
20L
24L
21

Fig. 2

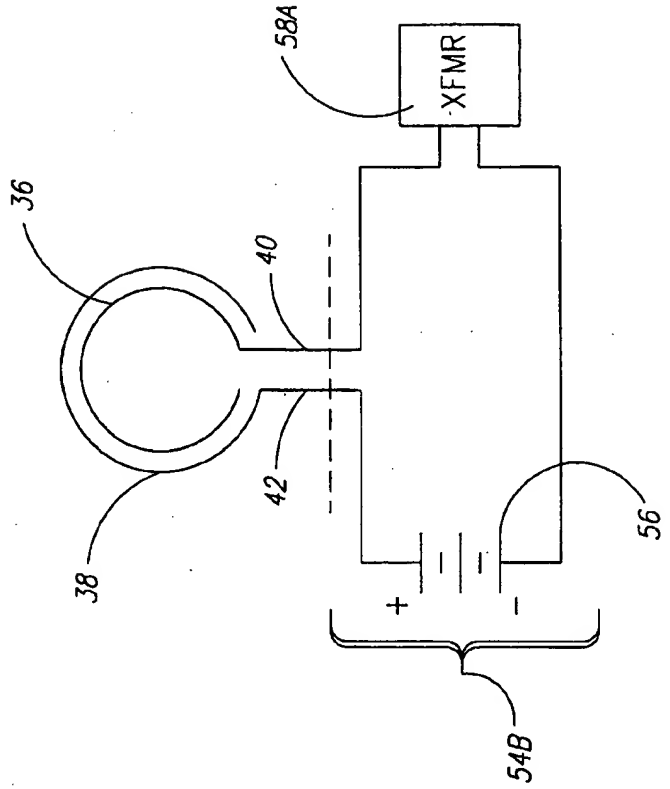

Fig. 5

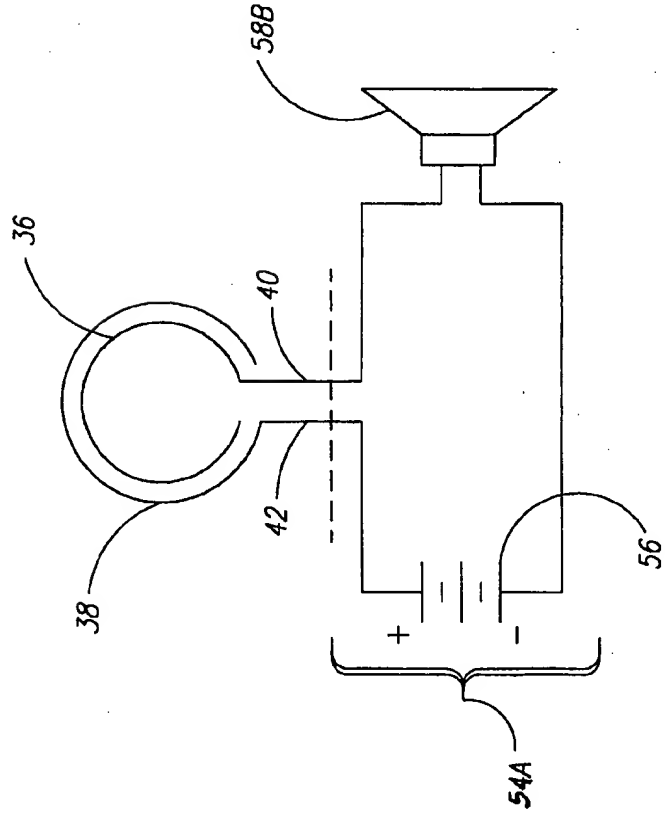

Fig. 4

MONITOR TO DETECT BLEEDING

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a disposable bandage designed to quickly detect and alert medical personnel of external bleeding in post angioplasty patients. More specifically, the present invention relates to a bandage within which is provided an open D.C. circuit capable of being closed by the patient's blood in order to activate an alarm.

2. Description of the Related Art

A variety of medical procedures involve puncturing of a large artery. Some of these procedures are Cardiac Catheterization (also known as Left Heart Catheterization, LHC, Coronary Angiography, or Coronary Arteriogram), Percutaneous Transluminal Angioplasty (also known as PTA), Percutaneous Transluminal Coronary Angioplasty (also known as PTCA), Percutaneous Coronary Atherectomy, Directional Atherectomy, Percutaneous Transluminal Coronary Rotoblator, Stents (including Renal, Biliary and Intracoronary Stents), and Electrophysiology Studies.

Typically the artery involved is either the Right or Left Femoral Artery. When the Femoral Arteries are not available, usually due to blockage, either the Left or Right Brachial Artery is normally used.

Generally, these procedures are done in order to increase blood flow in the body where the flow has become restricted due to the gradual buildup of plaque in the arteries.

The procedure is started by identifying the artery to be used. Then the site is shaved, cleaned, and an anesthetic agent is used to numb the area. A small scalpel blade is then used to make an incision through the skin. This allows access through the "tougher" layers of the skin. Then a large "needle" with a plastic sheath or tube (much like a large Intravenous Catheter) approximately six inches long (Atherectomy sheaths can be as long as 18 inches) is advanced into the chosen artery. When this is accomplished, the "needle" is removed from the sheath. This gives the doctor easy access from outside the body to the interior of the artery. Again, this is much like the process used when placing an IV catheter except for the much larger size of the "needle" and sheath. The sheath is also known as an Introducer, because the doctor is allowed to "introduce" wires into the artery via the sheath. The sheath is provided with a plug which prevents blood from flowing outside the patient's body, but through which specially designed wires can be inserted into and removed from the artery.

Once this is accomplished, the doctor is then able to thread a catheterization wire through the sheath, into the artery and into the coronary arteries. This wire is extremely small, typically a couple of millimeters in diameter. With this device, the doctor is able to inject a radiopaque dye into the coronary arteries. He may also inject dye into other arteries, if he chooses, by merely manipulating the wire to other parts of the body, for example, the renal arteries, biliary arteries, the aorta, the femoral arteries, or the carotid arteries.

If blockage of an artery is detected, the doctor may opt to intervene using one of the various methods available. All these methods are accomplished via special wires like the cardiac catheterization wires. Each special wire has unique fittings that accomplish the same goal, which is increasing blood flow, but each accomplishes this goal in a slightly different manner. The details of these different methods will not be reviewed herein since they are commonly known in the medical profession. Anticoagulants are administered to the patient when certain of these methods are employed in order to prevent undesirable blood clotting within the arteries.

Once the procedure is completed, the wire with its particular application end is removed from the body via the sheath. This leaves the patient with only a sheath in the artery again, at the puncture site. For patients that did not receive anticoagulants, the sheath is generally removed immediately after the procedure, pressure is held and then the patient recovers after a specified number of hours of bed rest. If the patient received anticoagulants after any procedure, the effect of the anticoagulant must be allowed to lessen before the sheath/introducer is removed, pressure is applied and the patient is then required to remain on bed rest for a specified number of hours while he recovers.

Nursing care during this period of bed rest involves visual and tactile assessment of the puncture site. These assessments occur quite frequently at first, generally about every 15 minutes, and occur less frequently during the course of the patient's care, ending with assessments occurring as infrequently as two hours apart.

In addition to the visual and tactile assessments, most patients are also monitored continuously during this period of time with an electrocardiograph (ECG), either at the bedside or via a remote system. However, if the patient were to begin hemorrhaging from the puncture site, substantial loss of blood generally occurs before the ECG registers any significant and noticeable changes which would alert the nursing staff of a problem. If the patient is asleep when his puncture site begins to bleed, and therefore, unable to call the nursing staff for help, substantial loss of blood can occur before the bleeding is detected.

Currently, there is no means, other than depending on the patient to call the nurses when he begins to bleed, for detecting this type of bleeding early enough to prevent the patient from losing a large volume of blood.

The present invention addresses this need by providing a disposable bandage which is applied over the puncture site and which is equipped with electrical means for detecting bleeding and activating an alarm when bleeding is detected. The present invention is provided with a clear observation window which allows visual and tactile assessment of the puncture site without removing the invention from the patient. The invention is also provided with a flexible segment which connects that portion of the invention which covers the puncture site and another portion of the invention which holds the power source and alarm mechanism. This flexible segment allows the two connected portions to be positioned on the patient's skin in order to allow the patient to be mobile without dislodging or disconnecting the invention.

SUMMARY OF THE INVENTION

The present invention is a monitor for detecting external bleeding on a patient. The monitor has two self-sticking portions, a bandage portion and a holder portion, which attach to the patient by means of a self-sticking backing provided on an underside of each of the portions. The two portions are connected by a flexible connecting strip which serves as a flexible bridge for two wires which each run between the two portions. The bandage portion is provided with a gauze layer which lies against the patient so the gauze layer is between the patient and a first coiled end of each

wire. The bandage portion and the gauze layer are provided respectively with a bandage opening and gauze opening so that the two openings coincide with each other. A transparent window seals the openings so that a puncture site on the patient can be observed therethrough.

A second connecting end provided on each wire removably connects to a portable alarm device secured within a pocket provided on the holder portion. The portable alarm device contains a power source, preferably a 9-volt battery, and an alarm comprised of either an audible alarm or a transmitter for remotely producing a signal to alert medical personnel. The power source and alarm are connected together and with the wires to form a normally open electrical series circuit. If bleeding occurs, the electrically conductive blood completes the circuit where it is open between the first coiled ends, thereby supplying electricity to the alarm to activate it.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a monitor to detect bleeding constructed in accordance with a preferred embodiment of the present invention as it would appear in use on a patient.

FIG. **2** is a bottom plan view of the invention of FIG. **1** with the backing layer removed from the connecting strip in order to reveal the wires.

FIG. **3** is a cross-sectional view taken along line **3**—**3** of FIG. **2**.

FIG. **4** is a schematic diagram illustrating the electrical arrangement of the two wires, the battery and the alarm of a preferred embodiment of the present invention where the alarm is an audible type alarm.

FIG. **5** is a schematic diagram illustrating an alternate electrical arrangement of the two wires, the battery and the alarm where the alarm is a transmitter which activates a signal remotely.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings and initially to FIGS. **1** and **2**, there is illustrated a monitor **10** for detecting bleeding in a post-angioplasty patient **12**. Although use of the monitor **10** is described for use on a post-angioplasty patient **12**, it is contemplated that the monitor **10** could be employed with any patient having wounds, particularly those involving arterial invasion, which need to be closely monitored for bleeding. As shown in FIG. **1**, the monitor **10** consists of a bandage portion **14** and an opposite holder portion **16** which connect together by means of a flexible connecting strip **18**, as will be explained more fully hereafter.

The bandage portion **14** is provided with outwardly extending left and right bandage wings **20**L and **20**R formed of a flexible material **21** which is provided with self-sticking adhesive on an underside **22** of the flexible material **21**, such as the plastic type of material used for commercially available adhesive bandages. The holder portion **16** is also provided with outwardly extending left and right holder wings **24**L and **24**R formed of the flexible material **21** which has a self-sticking adhesive on its underside **22**. Likewise, the connecting strip is formed of the flexible material **21** whose underside **22** is provided with a self-sticking adhesive. In fact, as illustrated in the preferred embodiment of the invention shown in FIGS. **2** and **3**, the bandage portion **14**, the holder portion **16**, and the connecting strip **18** are all formed from a continuous piece of the flexible material **21** which has self-sticking adhesive on its underside **22**.

Referring now to FIG. **1**, the material **21** forms a top surface **26** of the bandage portion **14** and its underside **22** forms a bottom surface **27** of the bandage portion **14**. The bandage portion **14** is provided with a central bandage opening **28**. A clear observation window **30** is provided attached to the bandage portion **14** so that the window **30** completely covers and seals the central bandage opening **28**.

A gauze layer **32** which is somewhat smaller than the bandage portion **14** and is provided with a central gauze opening **34** which coincides with the central bandage opening **28**, is attached on the bottom surface **27** of the bandage portion **14**. The gauze layer fully encircles the bandage opening in order to protect the patient **12** from contact with coiled ends **36** and **38** of first and second electrical wires **40** and **42** which are provided concentrically around the central bandage opening **28** and located between the gauze layer **32** and the bottom surface **27** as will be more fully explained hereafter.

The coiled ends **36** and **38** are spaced apart from each other, with the first coiled end **36** located between the central bandage opening **28** and the second coiled end **38**. Neither of the coiled ends **36** and **38** contacts its respective wire **40** or **42** or the wire **42** or **40** of the other coiled end **38** or **36**.

The wires **40** and **42** extend from their respective coiled ends **36** and **38**, parallel with one another along a bottom surface **44** of the connecting strip **18**, through a strip opening **46** provided in the connecting strip **18** adjacent the holder portion **16** to a top surface **48** of the holder portion **16**. Each of wires **40** and **42** is provided with a connecting end, **50** and **52** respectively, located on the top surface **48** of the holder portion **16**. Each of the connecting ends **50** and **52** are removably connectable to a portable alarm device **54**. A variety of different types of portable alarm devices **54** may be used for this purpose. As illustrated in FIGS. **4** and **5**, each such portable alarm device **54** will be provided with a battery power supply **56**, preferably a 9-volt battery, connected in series with the two wires **40** and **42** via their connecting ends **50** and **52** and also connected in series with an alarm **58**. Everything in FIGS. **4** and **5** below the broken lines is included within the portable alarm device **54**. As illustrated in FIG. **5**, the portable alarm device **54**A may have as its alarm **58** a transmitter device **58**A for remotely alerting the nursing staff of a problem or, as shown in FIG. **4**, the portable alarm device **54**B may have as its alarm **58** an audio alarm **58**B, such as a piezo-type pulsating alarm, designed to produce a loud warning siren. The wires **40** and **42** form a normally open electrical circuit between the power supply **56** and the alarm **58**.

The top surface **48** of the holder portion **16** is provided with a pocket **59** which holds the portable alarm device **54** against the top surface **48**, even when the patient **12** moves around. In order to prevent the portable alarm device **54** from slipping out of the pocket **59**, the pocket **59** is provided with a pocket closure **61** which serves to close the pocket **59**, preventing the portable alarm device **54** from coming out of the pocket **59** until the pocket closure **61** is reopened. The pocket closure **61** may be any type of closure capable of being sealed and reopened. The pocket **59** is preferably provided with pocket openings **63** therethrough so that sound from an audio alarm **58**B can easily be heard by the patient **12**.

The bottom surface **44** of the connecting strip **18** is provided with a backing layer **60** which extends from the gauze layer **32** to preferably slightly beyond the strip open-

ing 46. The wires 40 and 42 are located between the bottom surface 44 and the backing layer 60, with the bottom surface 44 serving to shield the patient 12 from contact with the wires 40 and 42, as can be seen in FIG. 3.

As illustrated in FIG. 1, in order to use the monitor 10, the bandage portion 14 is attached to the patient 12 via its self-sticking bottom surface 24 so that a puncture site 62 resulting from a previously performed angioplasty or other similar medical procedure is centered in and visible through the transparent window 30. The holder portion 16 is then attached to the patient 12 via its self-sticking bottom surface 64 so that the connecting strip 18 is flexed upward, as shown in FIGS. 1 and 3. The purpose for having the connecting strip 18 flexed upward is to allow enough slack in the connecting strip 18 so that the bandage and holder portions 14 and 16 do not bind when the patient 12 moves around and so that the wires 40 and 42 are not thereby pulled out of electrical connection from the portable alarm device 54.

Once the monitor 10 has been properly attached to the patient 12, the gauze layer 32 serves to prevent perspiration of the patient 12 from reaching the coiled ends 36 and 38 of wires 40 and 42.

Both perspiration and blood are electrically conductive liquids, and if either is allowed to saturate the gauze layer 32 and reach the spaced apart coiled ends 36 and 38, this thereby completes or, forms an electrically closed circuit of the normally open electrical circuit existing between the battery power supply 56 and the alarm 58, thus causing the alarm 58 to activate.

If the patient 12 begins to hemorrhage from the puncture site 62, blood quickly completes the circuit between the coiled ends 36 and 38, thus causing the alarm 58 to activate. The activation of the alarm 58 immediately signals medical personnel that bleeding is occurring. Upon receiving the signal from the alarm 58, medical personnel can take quick action to stop the bleeding, generally by again applying direct pressure to the puncture site 62 in order to cause a clot to form.

At that point, the old monitor 10 is removed, the battery supply is removed for reuse, the old monitor 10 is properly discarded and a clean new monitor 10 is attached to the patient 12, as previously described.

While the invention has been described with a certain degree of particularity, it is manifest that many changes may be made in the details of construction and the arrangement of components without departing from the spirit and scope of this disclosure. It is understood that the invention is not limited to the embodiments set forth herein for purposes of exemplification, but is to be limited only by the scope of the attached claim or claims, including the full range of equivalency to which each element thereof is entitled.

What is claimed is:

1. A monitor for detecting bleeding comprising:

a bandage portion securable over a puncture site on a patient,

said bandage portion being provided with a central bandage opening therethrough, and

two spaced apart electrically conductive wires encircling said central bandage opening, each of said wires being electrically connected in series with a power supply and an alarm.

2. A monitor according to claim 1 further comprising:

a transparent window provided in said central bandage opening.

3. A monitor according to claim 1 wherein said wires are removably connected to a portable alarm device which is comprised of electrically connected said power supply and said alarm.

4. A monitor according to claim 3 wherein said power supply is a battery.

5. A monitor according to claim 1 further comprising:

a holder portion secured by means of a flexible connecting strip to said bandage portion, said wires each extending from said bandage portion across said connecting strip to said holder portion, holding means being provided on said holder portion for holding said power supply and said alarm.

6. A monitor according to claim 5 wherein both said holder portion and said bandage portion are provided with self-sticking bottom surfaces.

7. A monitor according to claim 1 further comprising:

a gauze layer being provided on a bottom surface of said bandage portion so that said gauze layer lies between the patient and said wires.

8. A monitor according to claim 7 further comprising:

said gauze layer being provided with a central gauze opening, said central gauze opening coinciding with said central bandage opening.

9. A disposable bandage for monitoring for bleeding from a puncture site of a post-angioplasty patient comprising:

a bandage portion securable over a puncture site on a patient,

said bandage portion being provided with a central bandage opening therethrough,

two spaced apart concentrically arranged electrical conductors encircling said bandage opening,

a first end of each two spaced apart concentrically arranged electrical conductors removably secured around the puncture site on the patient,

an opposite end of each said two electrical conductors being electrically connected in series with a power source and an alarm.

10. A bandage according to claim 9 further comprising:

said first ends of said electrical conductors being secured to said patient by means of the bandage portion, said bandage portion being provided with a transparent window covering the central bandage opening in said bandage portion so that the puncture site may be observed therethrough, said first ends being concentrically arranged around said bandage opening.

11. A bandage according to claim 10 wherein said power source and said alarm are removably connected to said electrical conductors.

12. A bandage according to claim 11 further comprising:

a holder portion attached to said bandage portion by means of a flexible connecting strip,

said holder portion securable to said patient, and

a holding means provided on said holder portion in order to secure said power source and said alarm to said holder portion.

* * * * *